

FIGURE 1

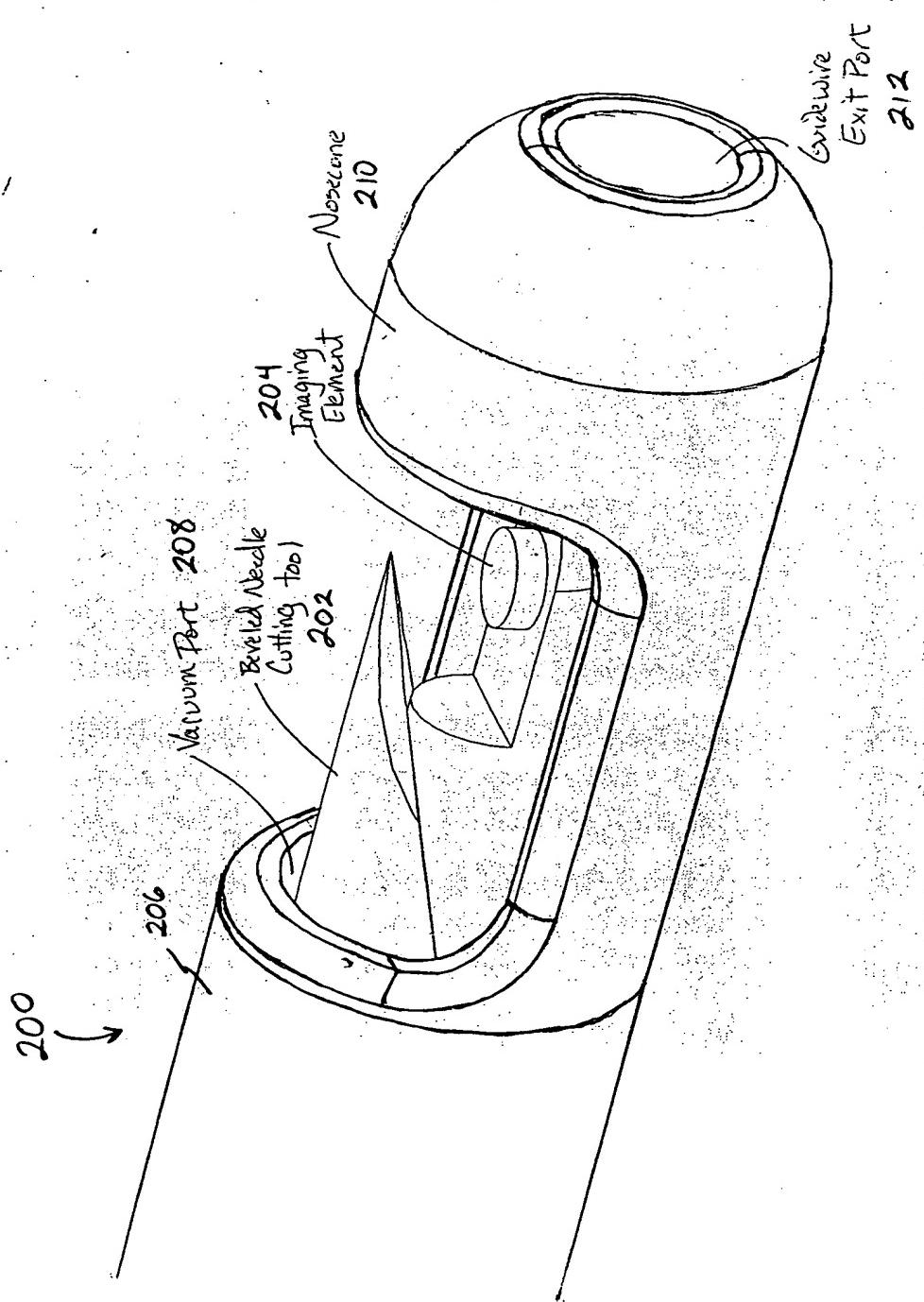


FIGURE 2

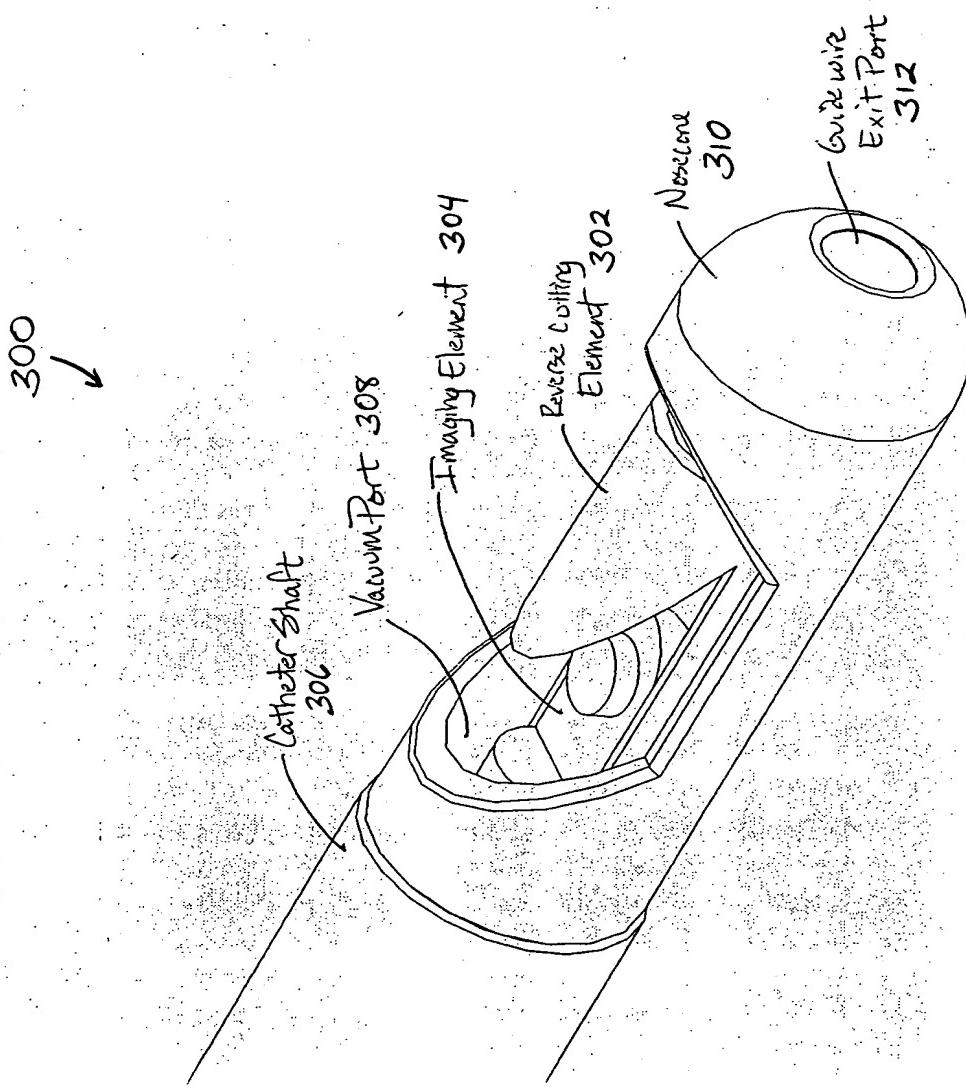


FIGURE 3

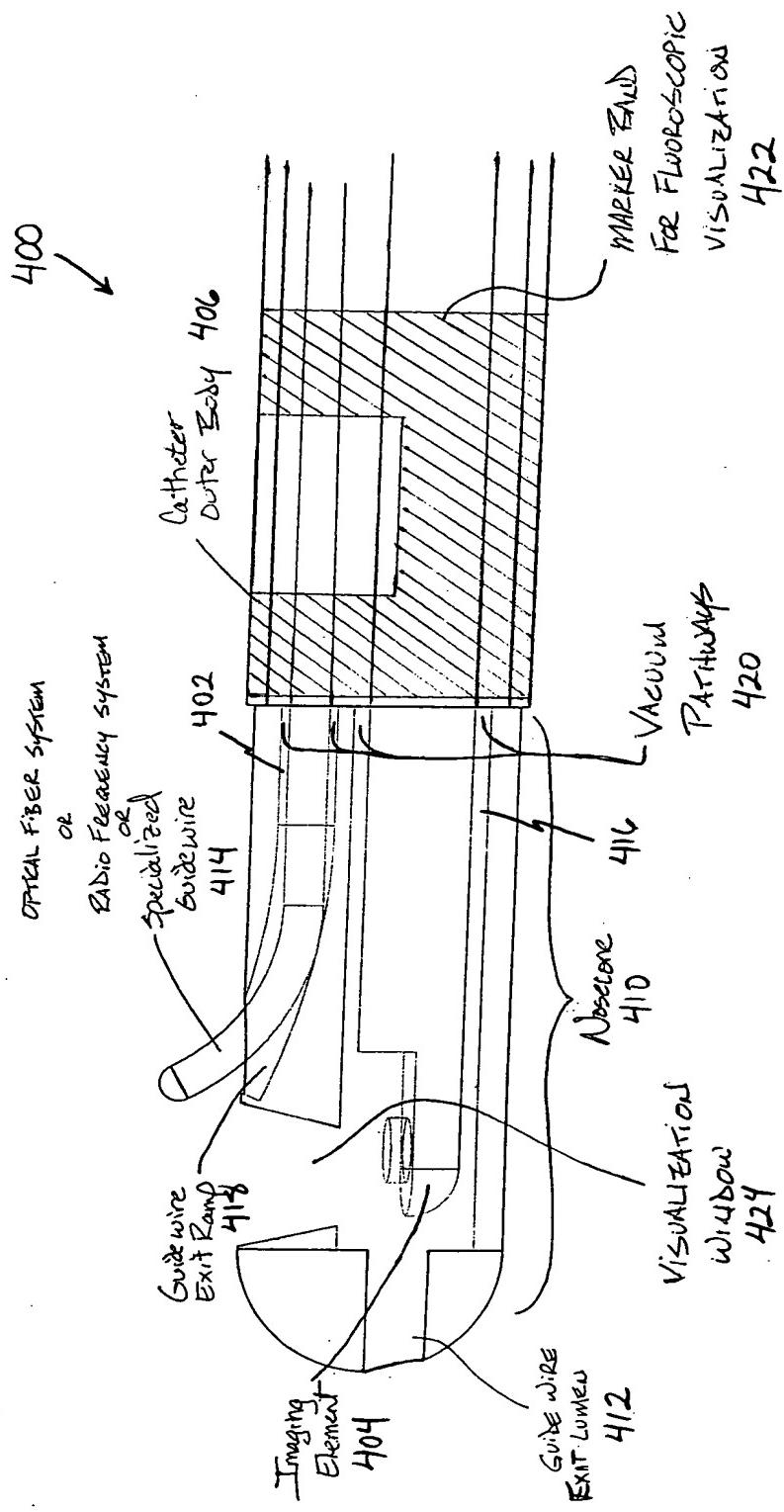


Figure 41

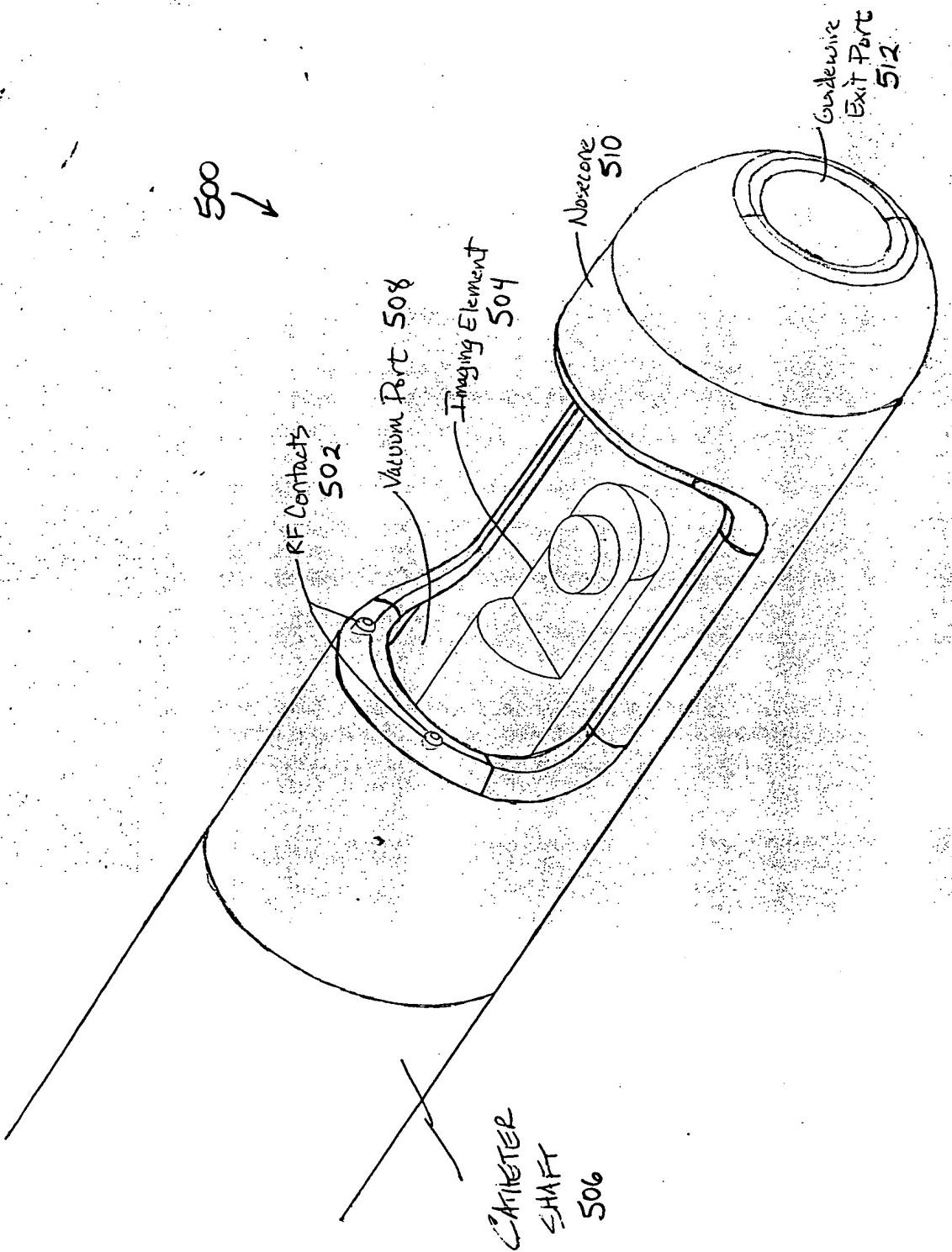


FIGURE 5

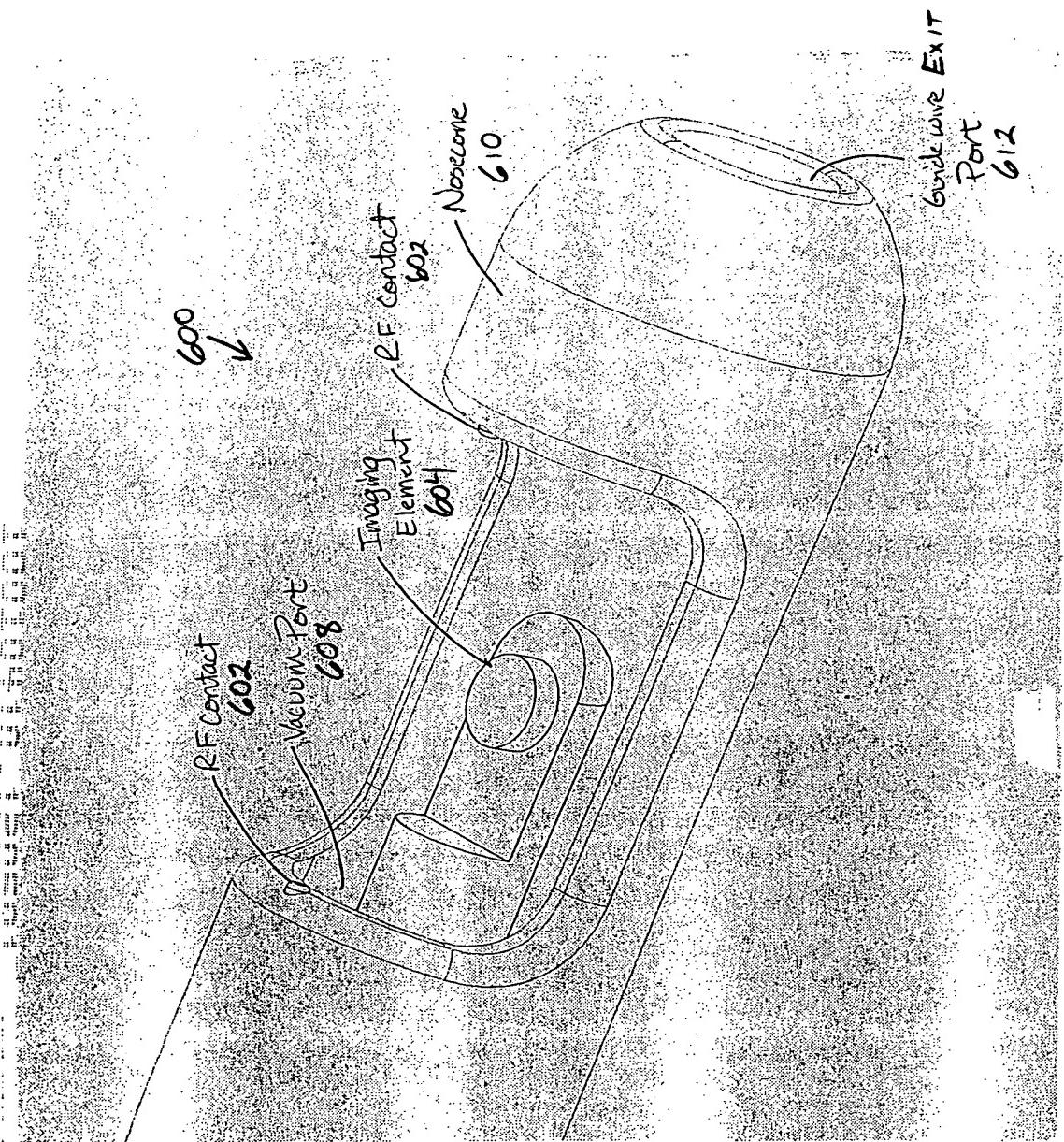


FIGURE 6

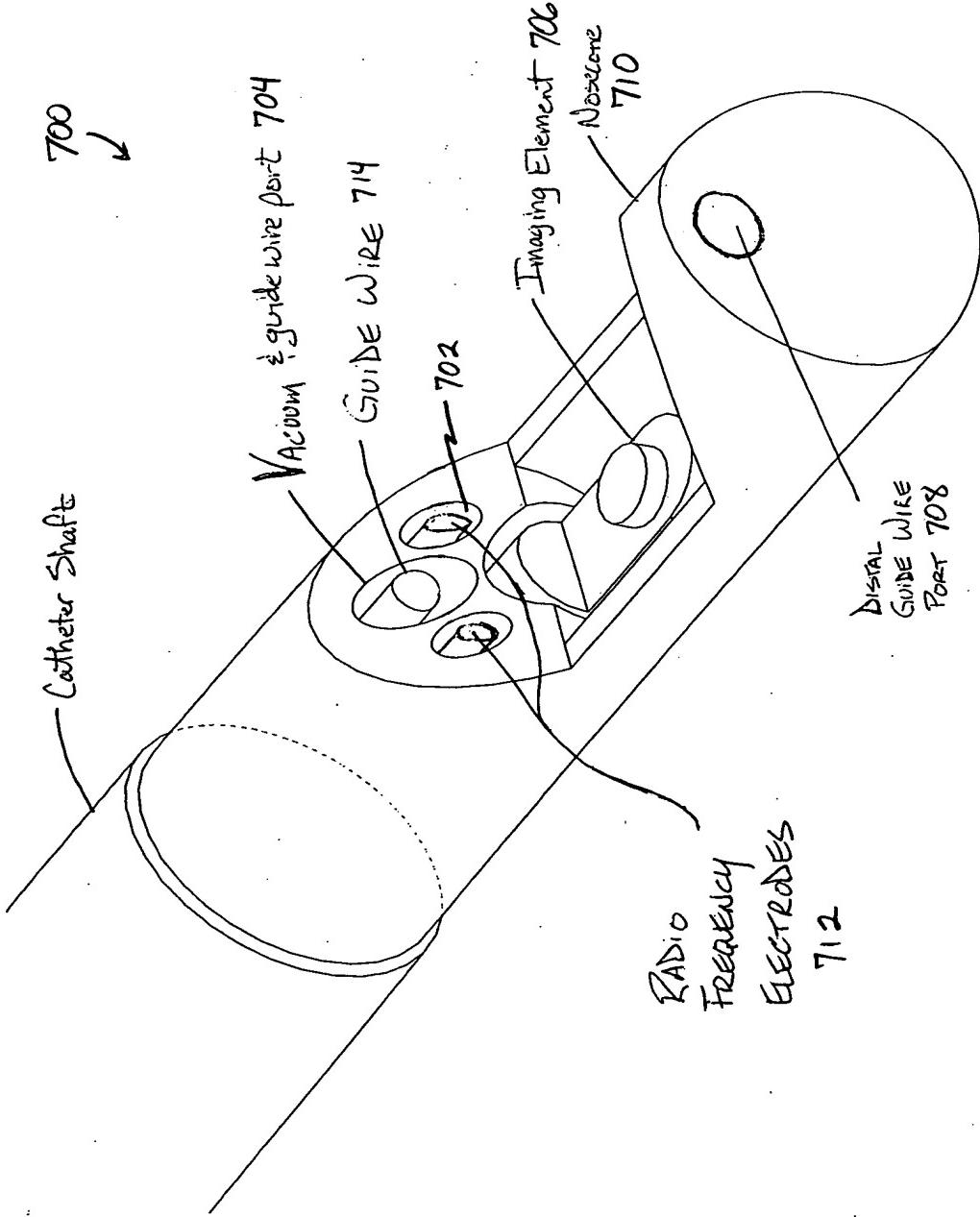


FIGURE 7A

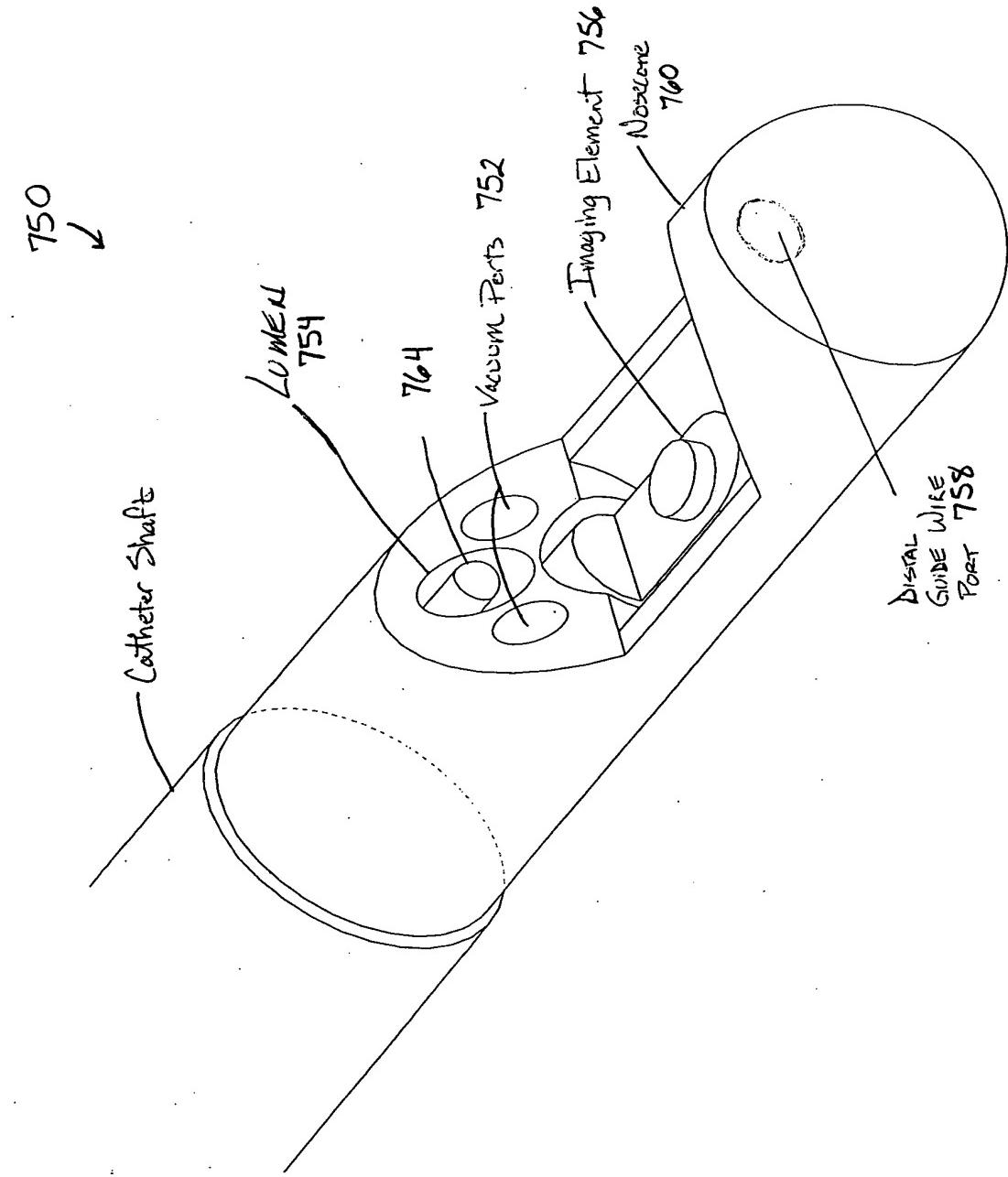


FIGURE 7B

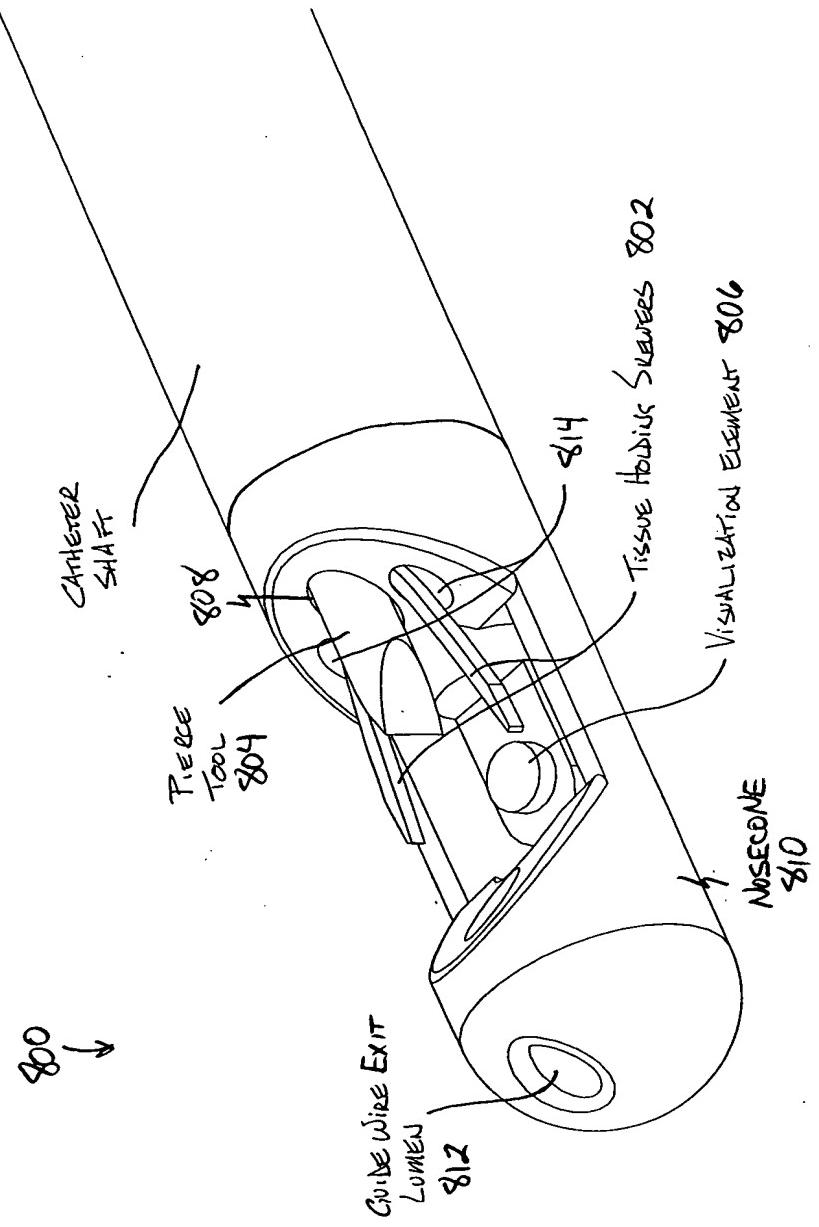


FIGURE 8

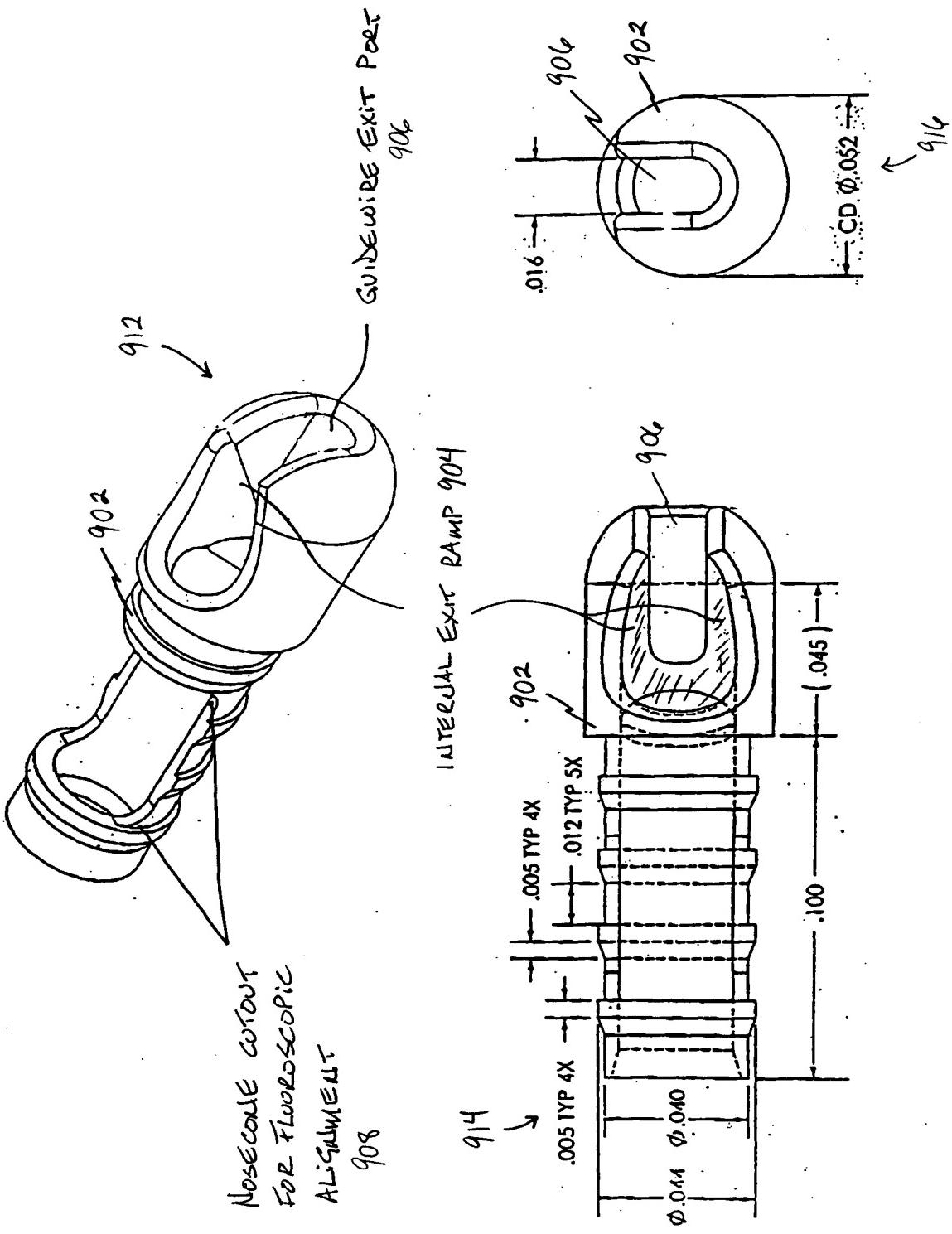
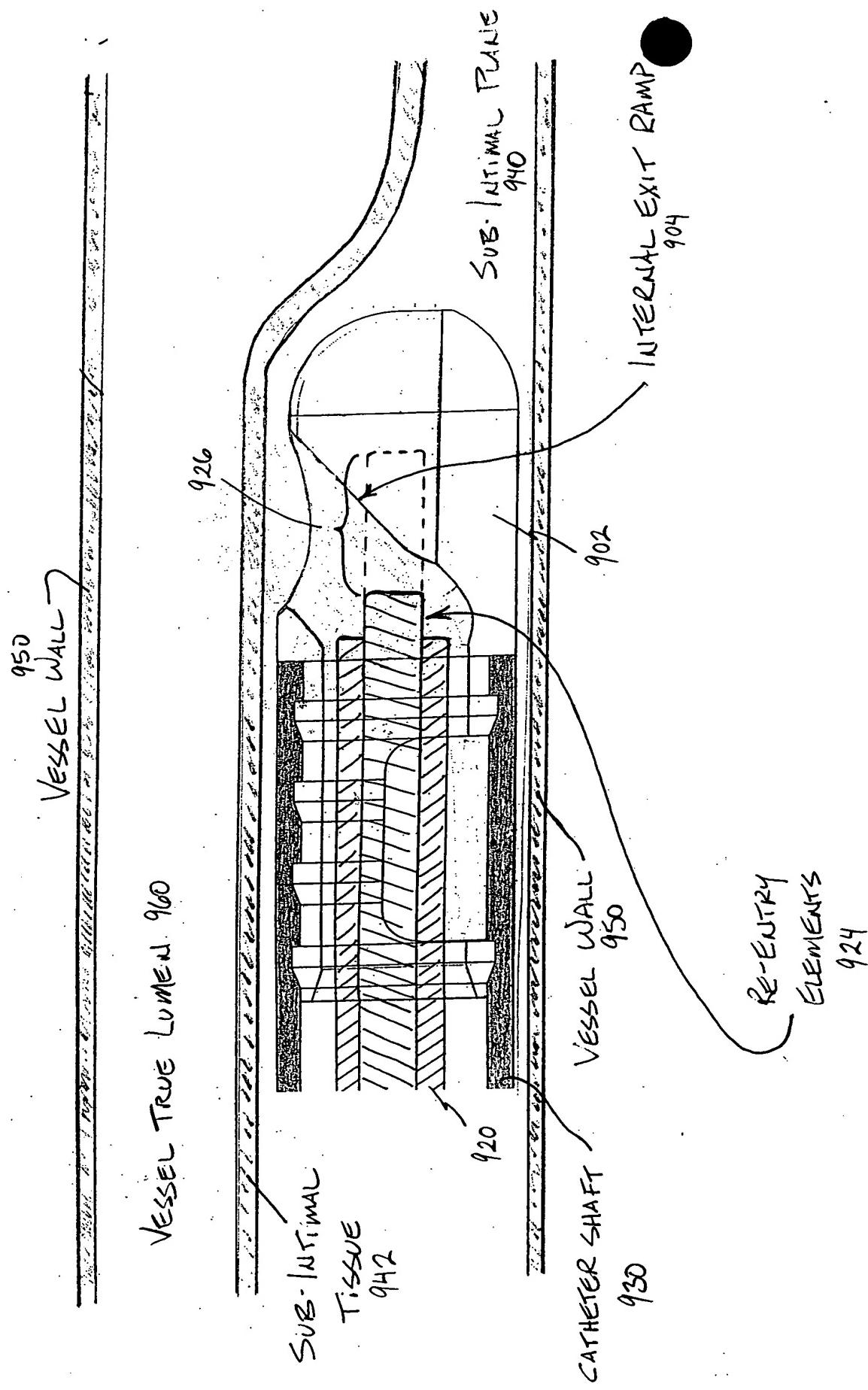


FIGURE 9A

FIGURE 9B



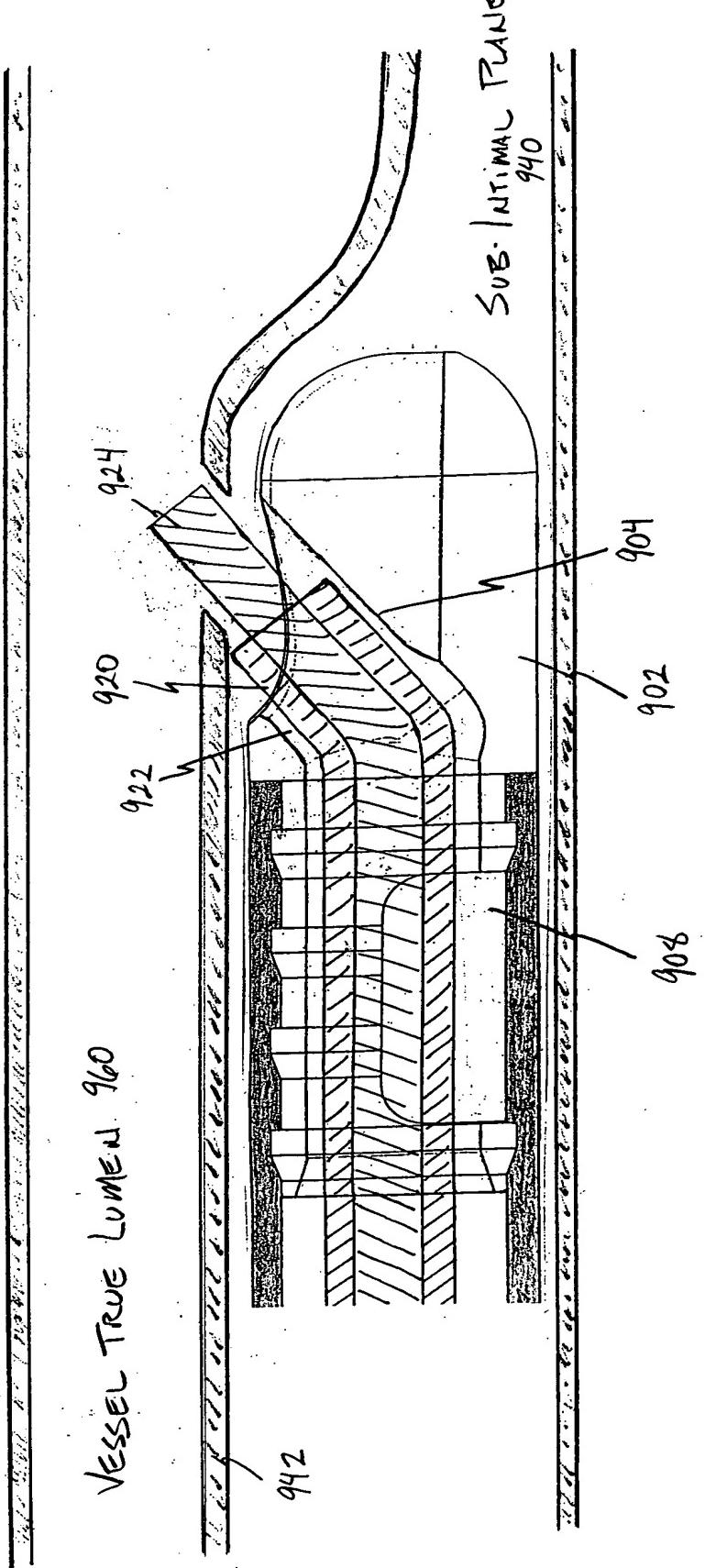
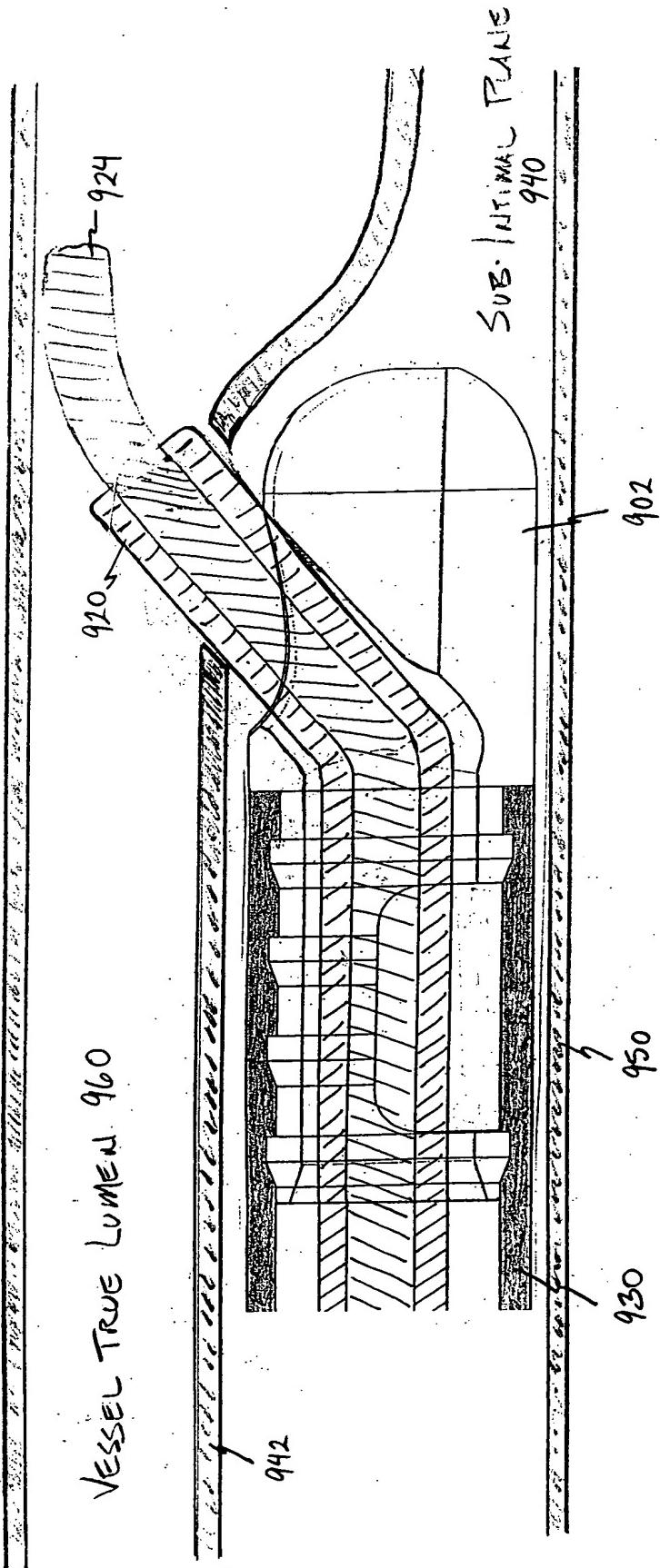


FIGURE 9C

FIGURE 9D



VESSEL TRUE LUMEN 960

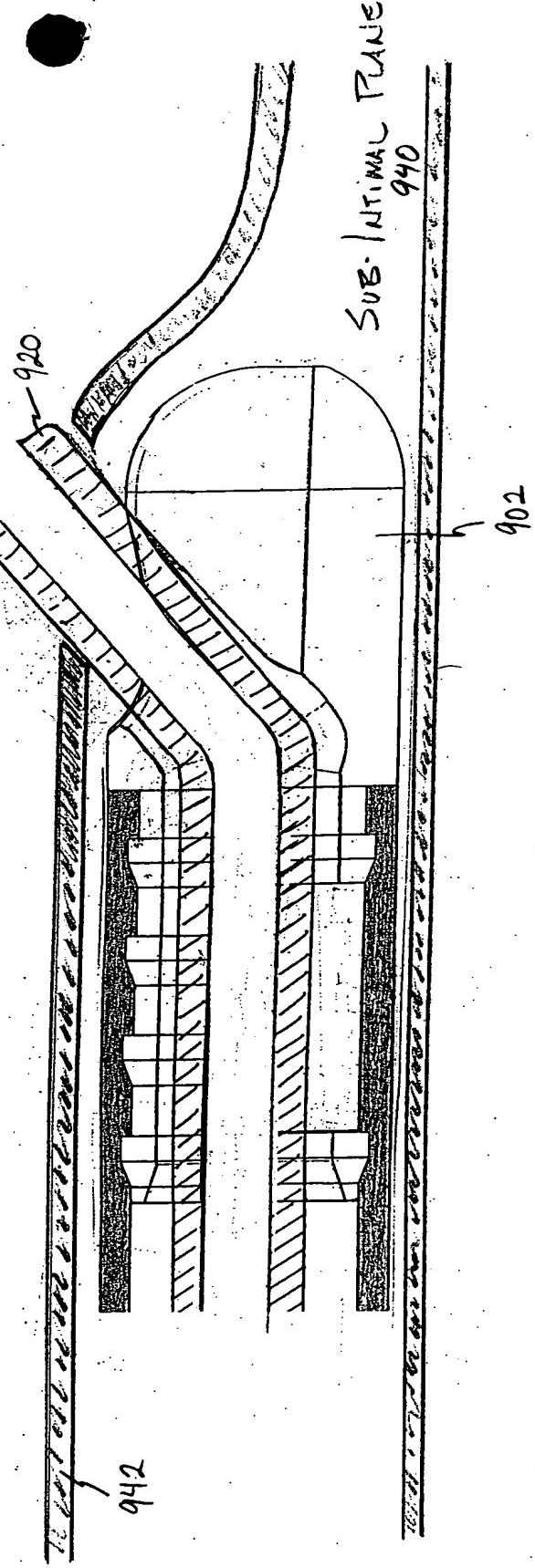


FIGURE 9E

FIGURE 9F

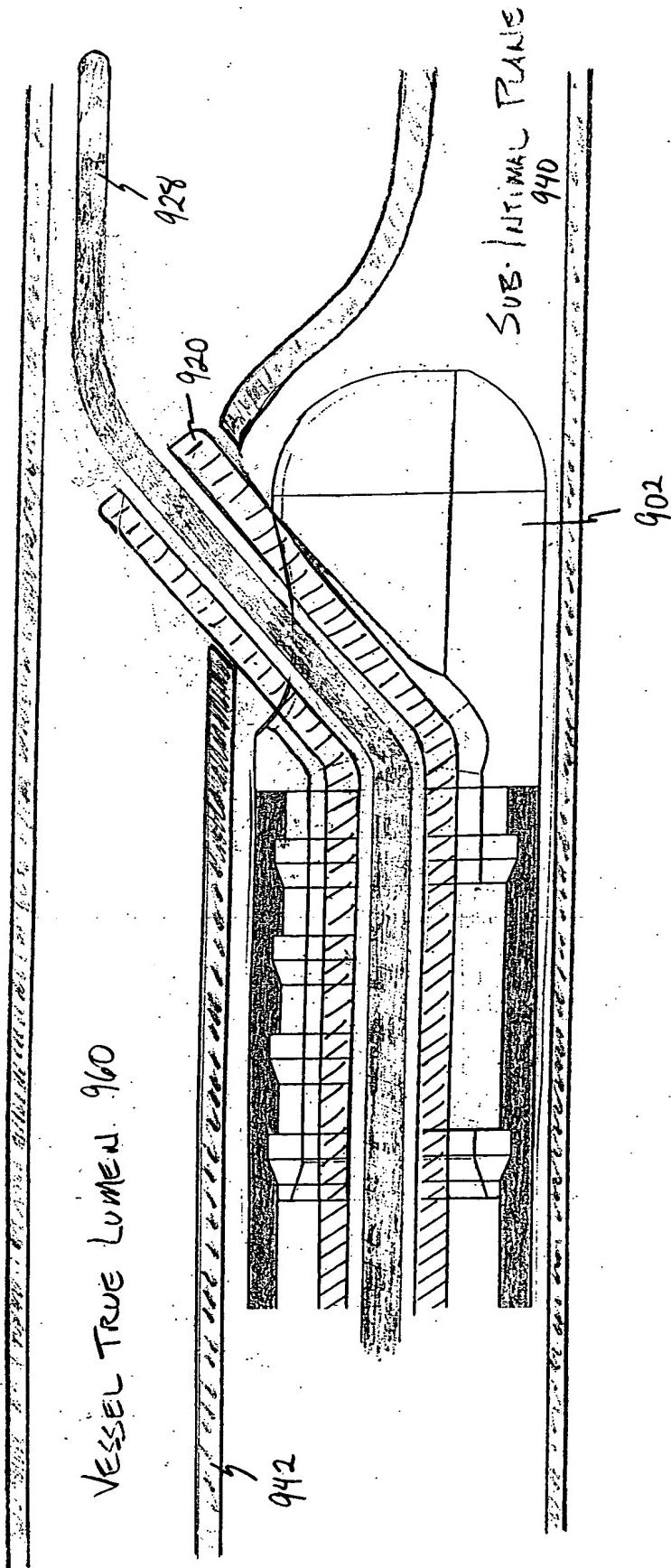
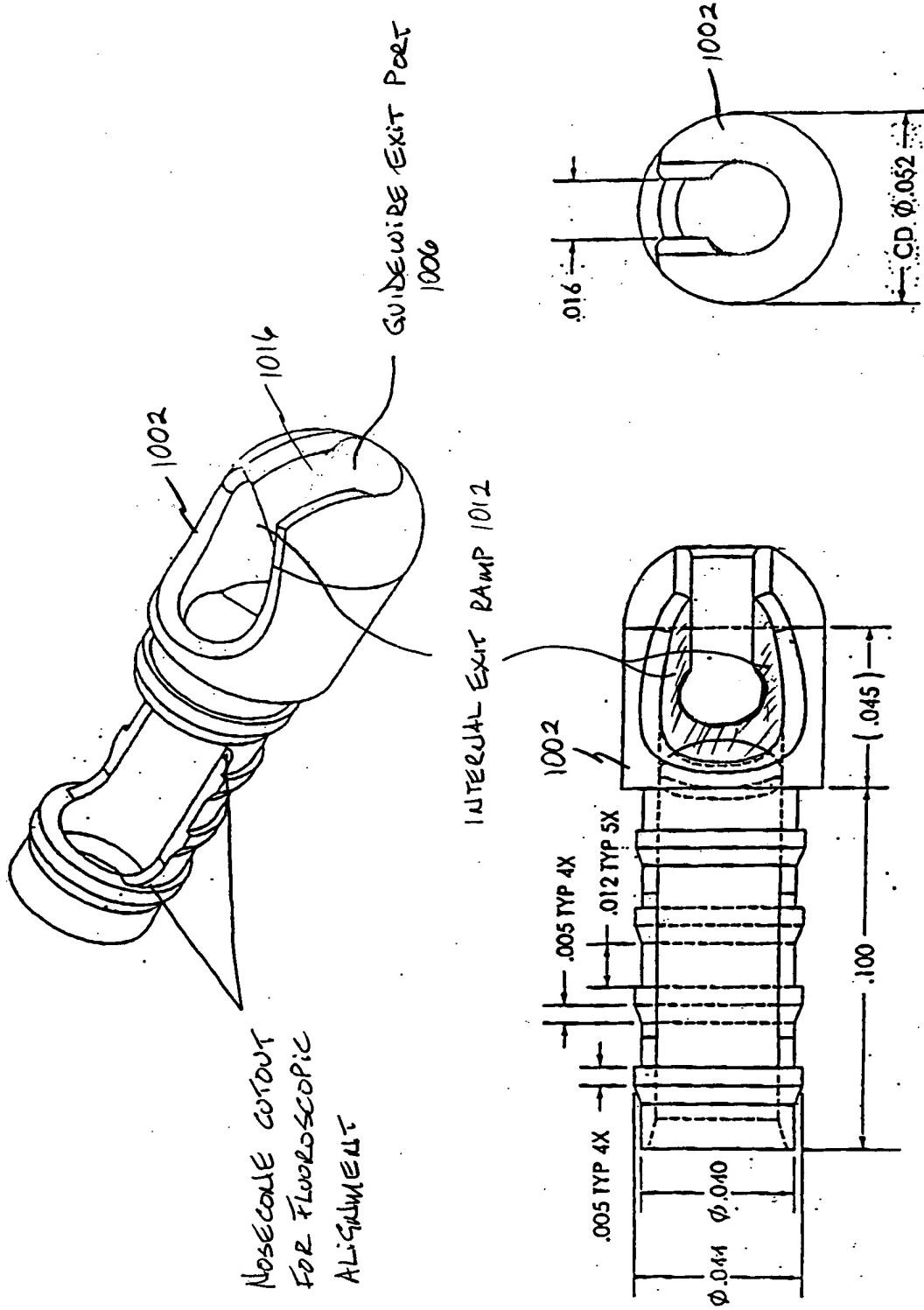


FIGURE 10A



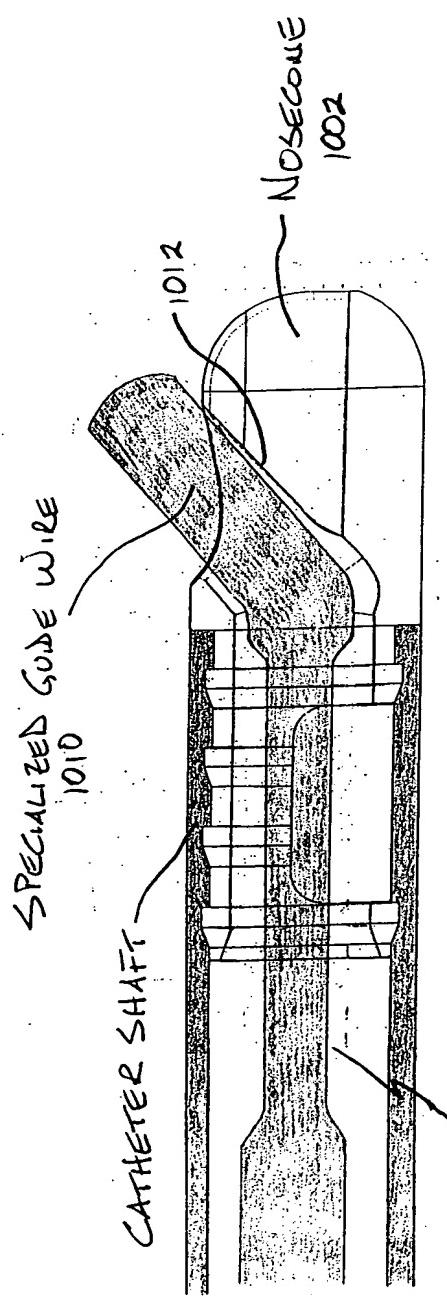


FIGURE 10B

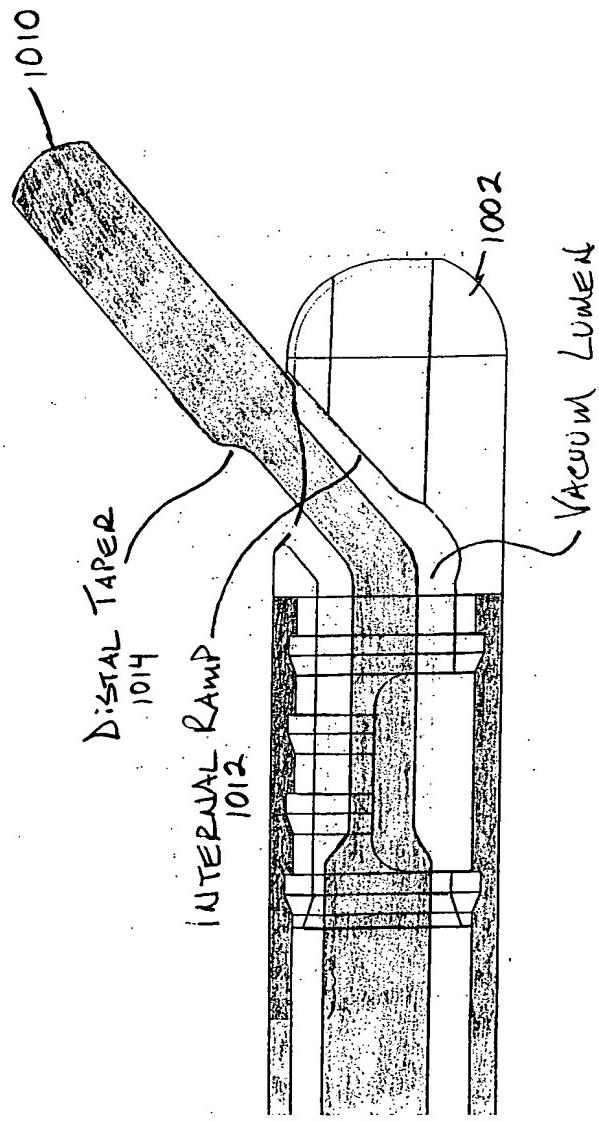


FIGURE 10C

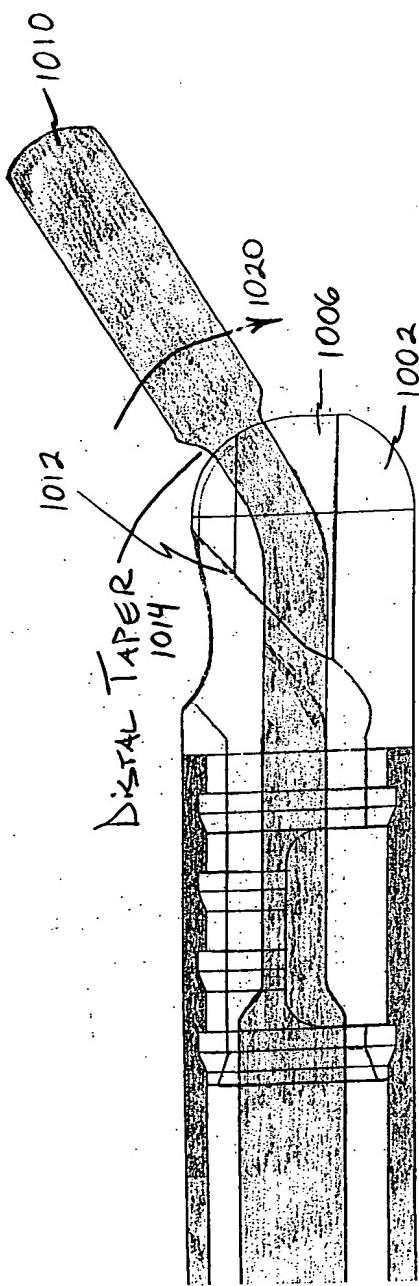


FIGURE 10D

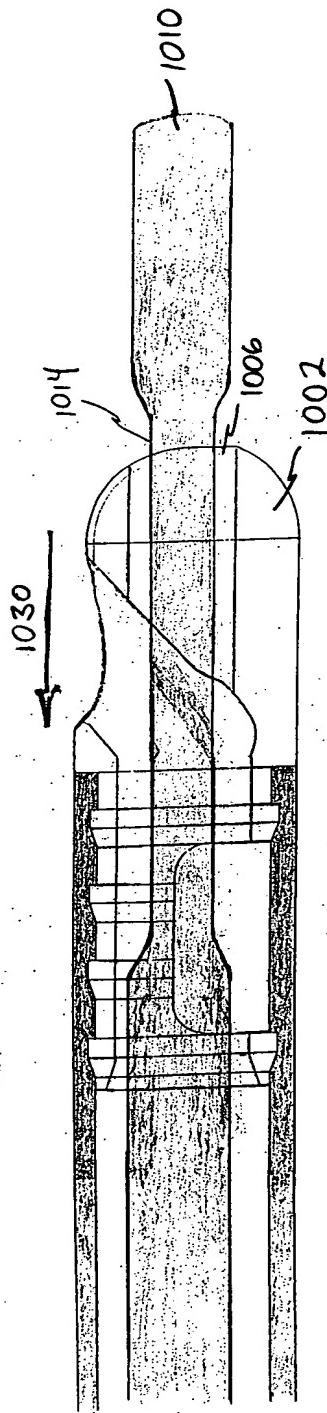
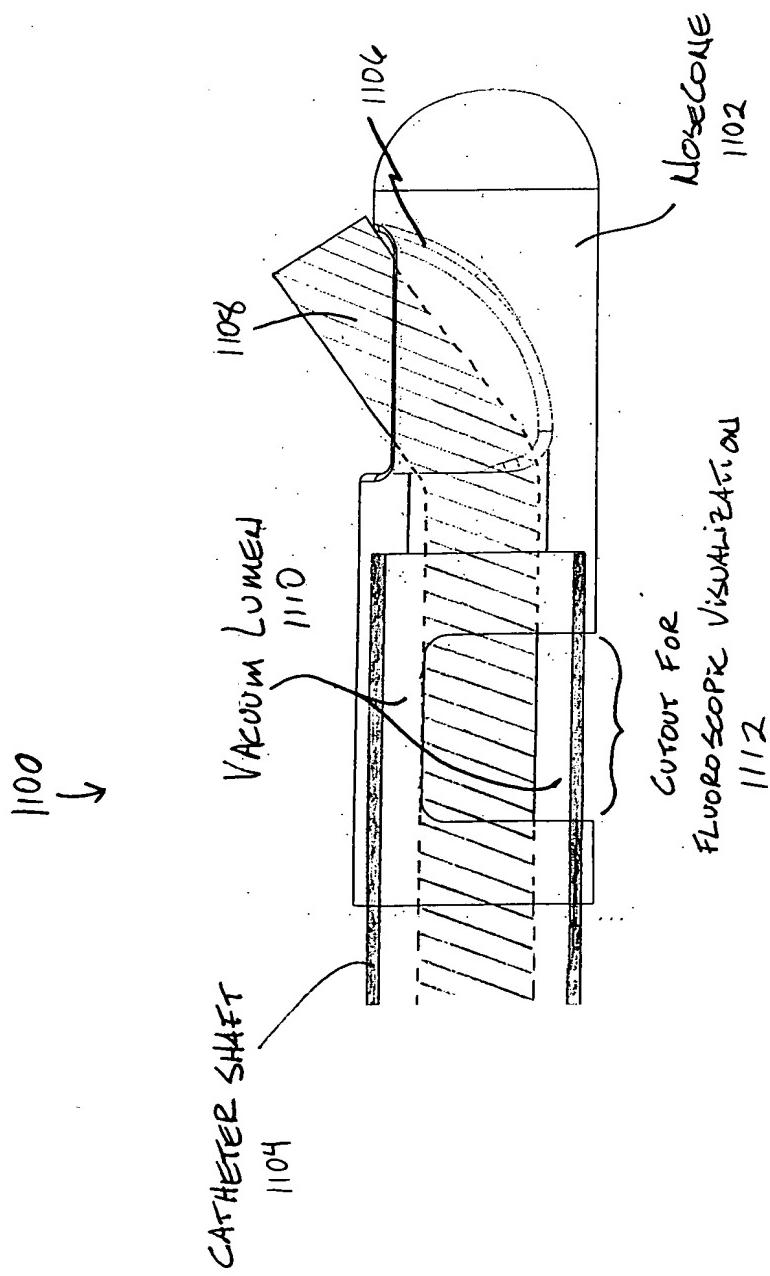


FIGURE 10E

FIGURE 11



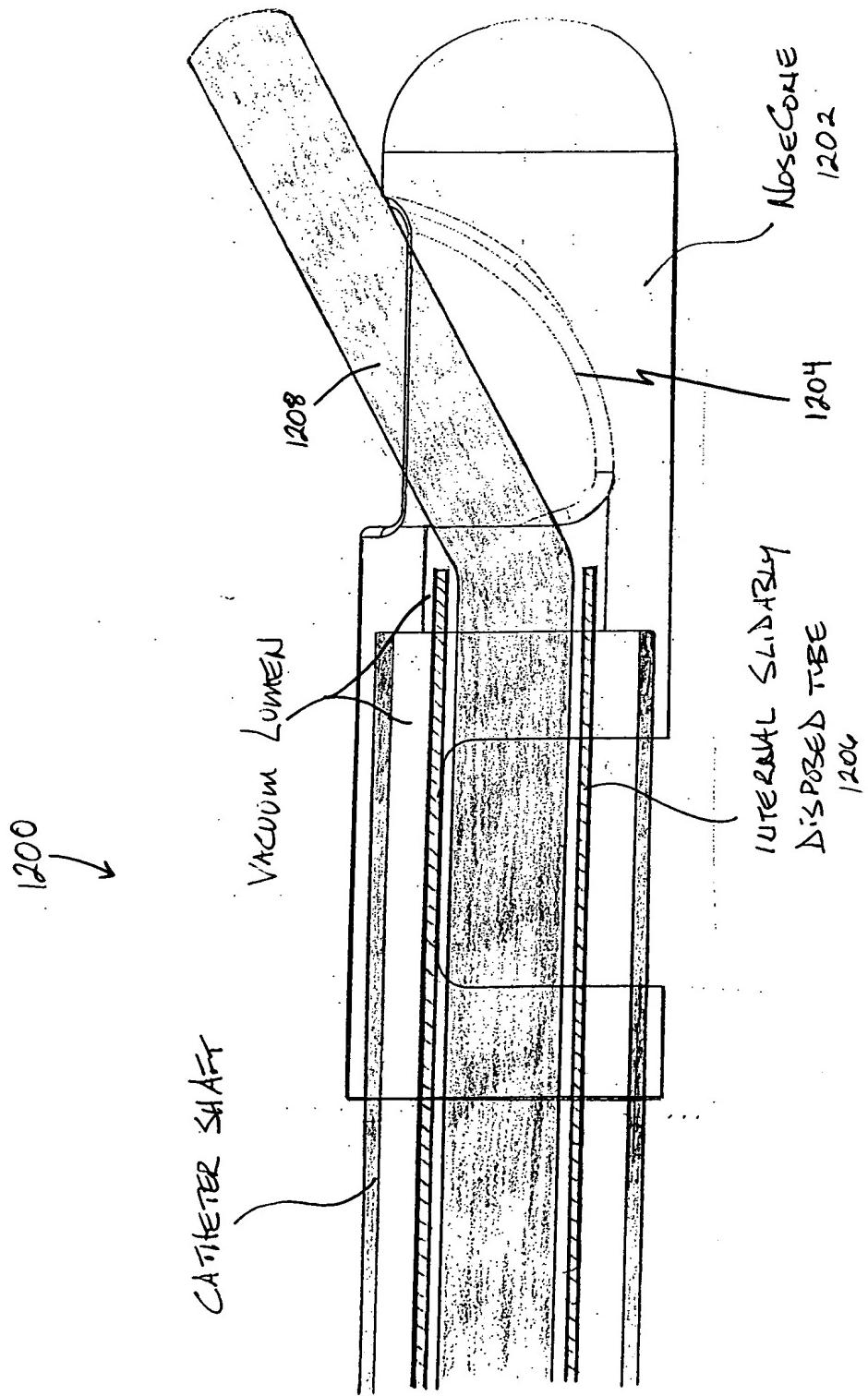


FIGURE 12A

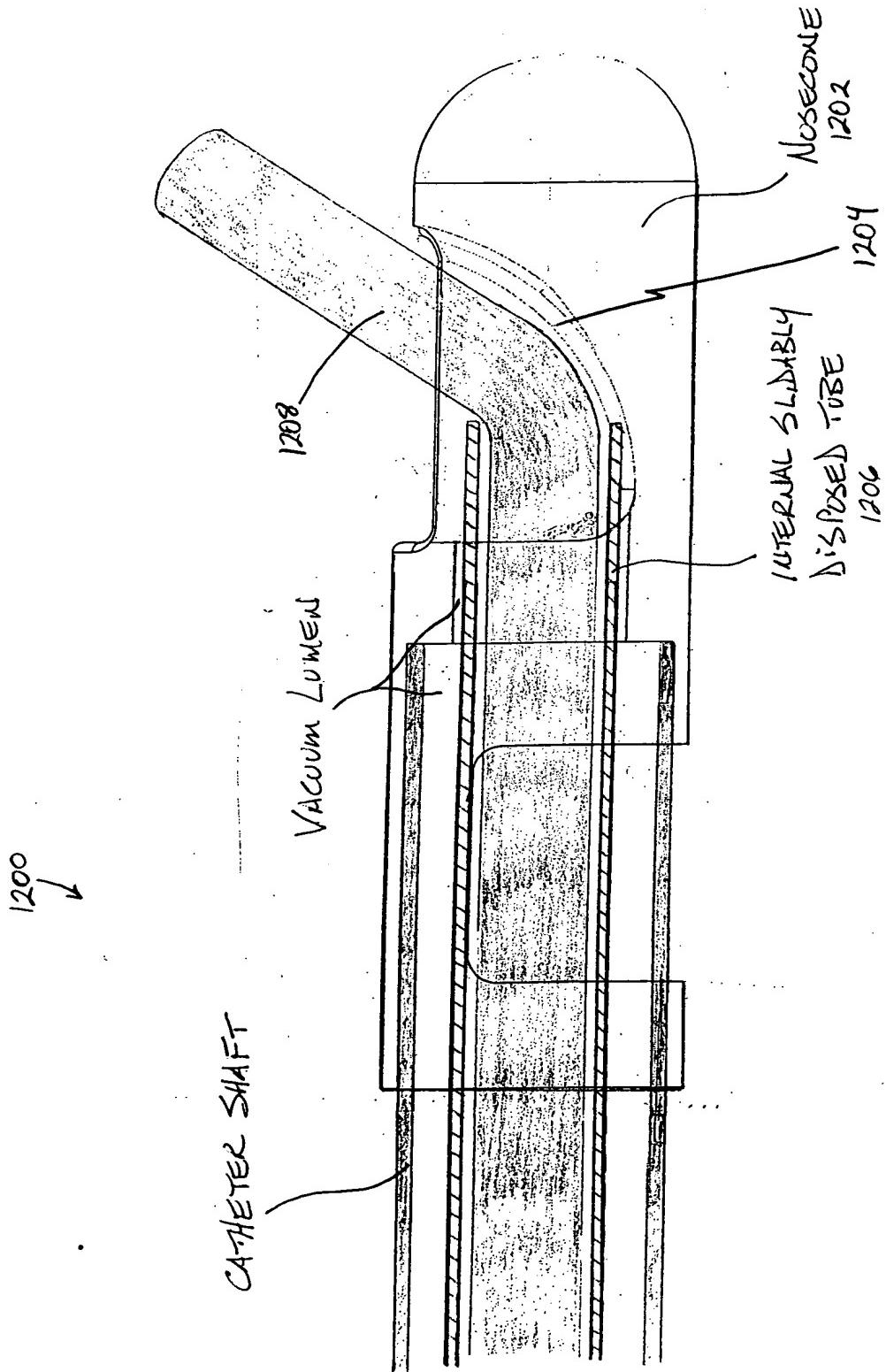
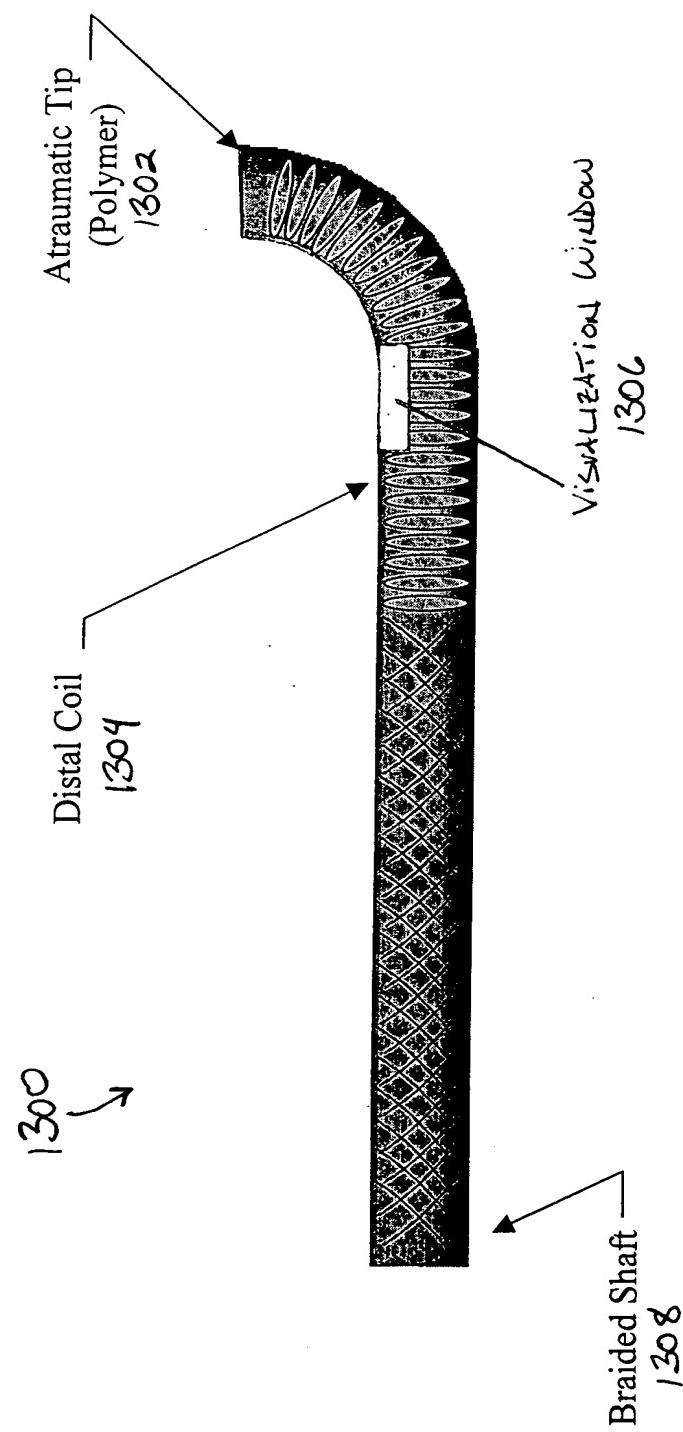


FIGURE 12B

FIGURE 13



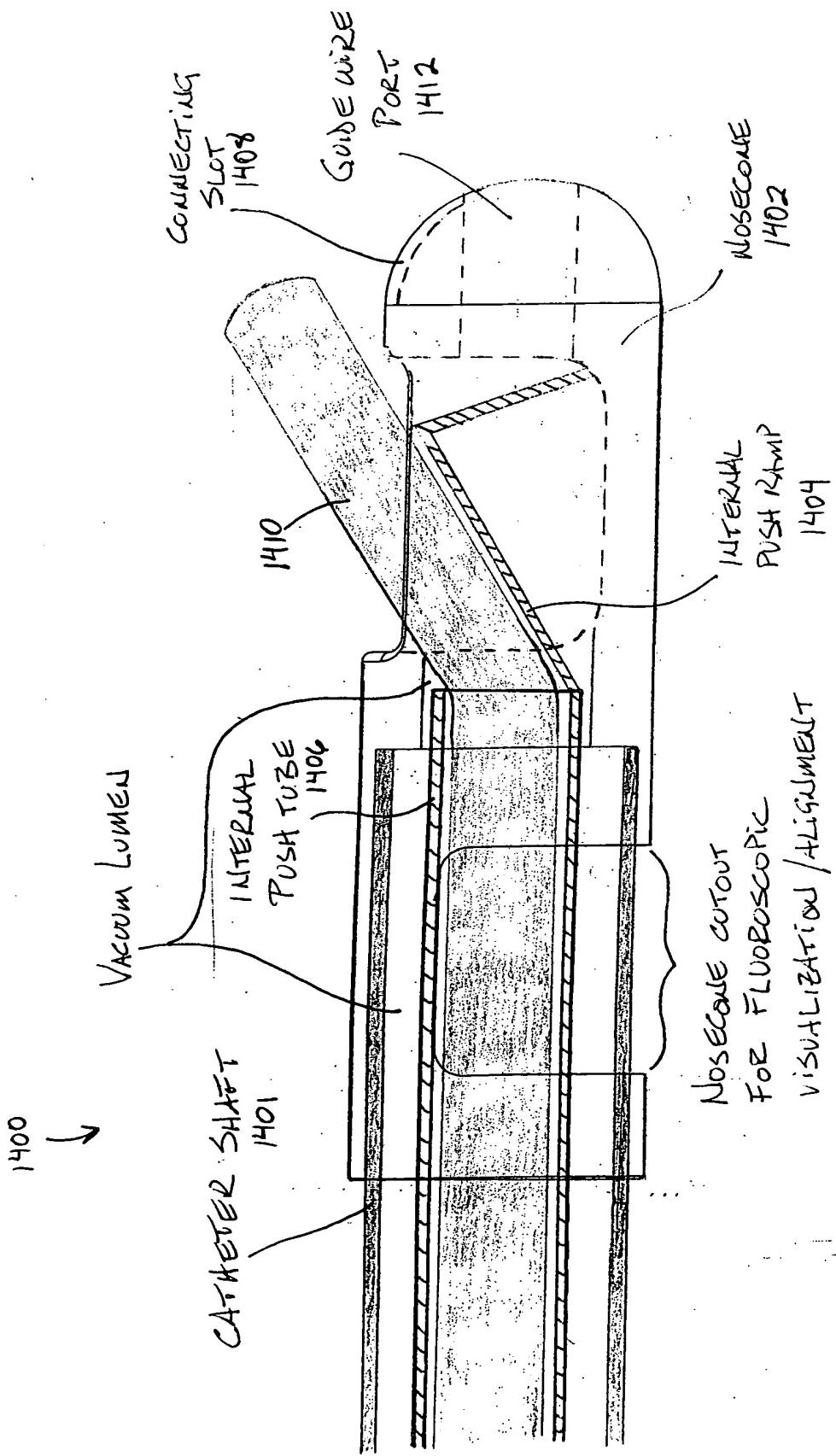


FIGURE 14A

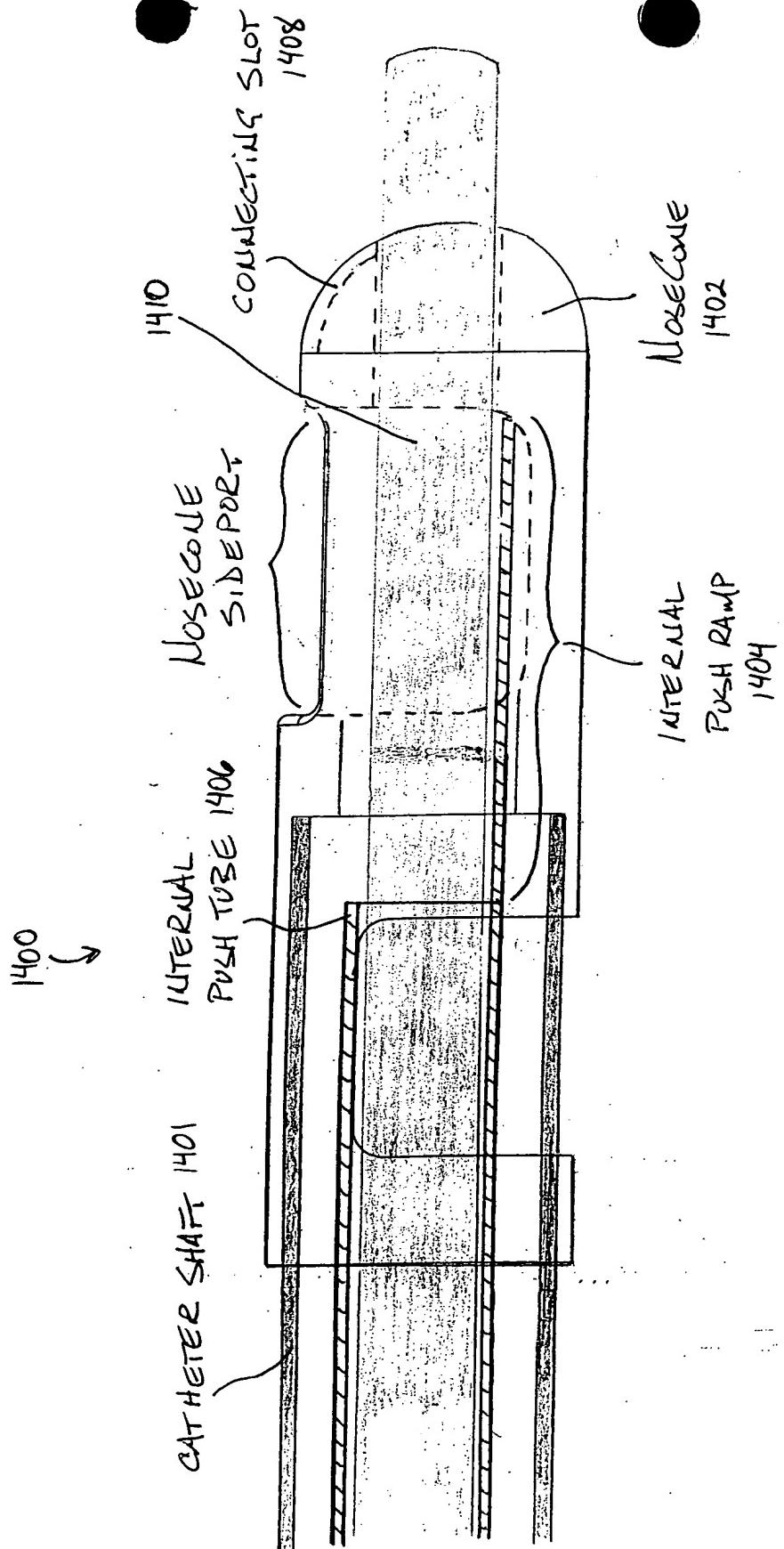


FIGURE 14B

FIGURE 15

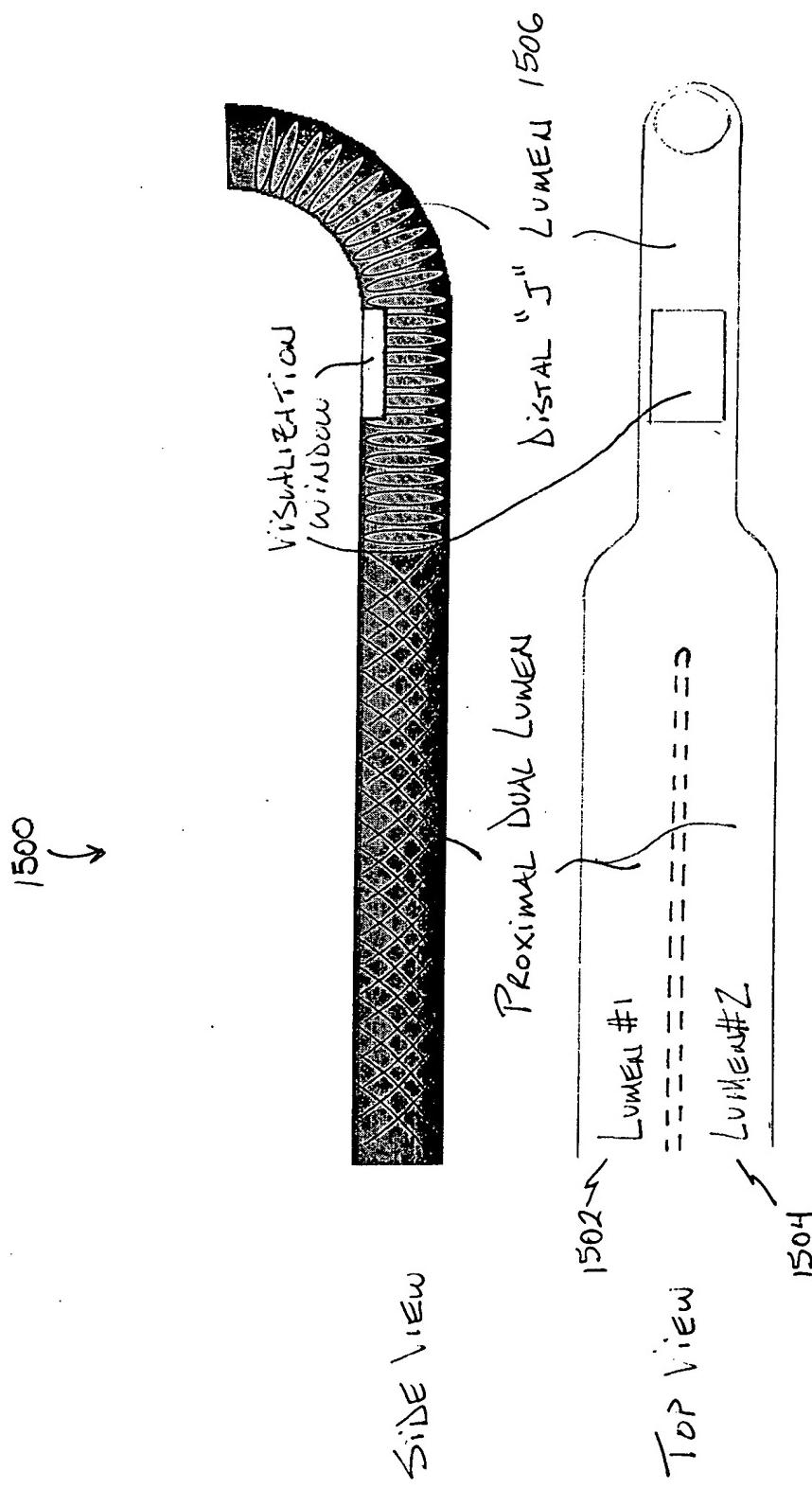
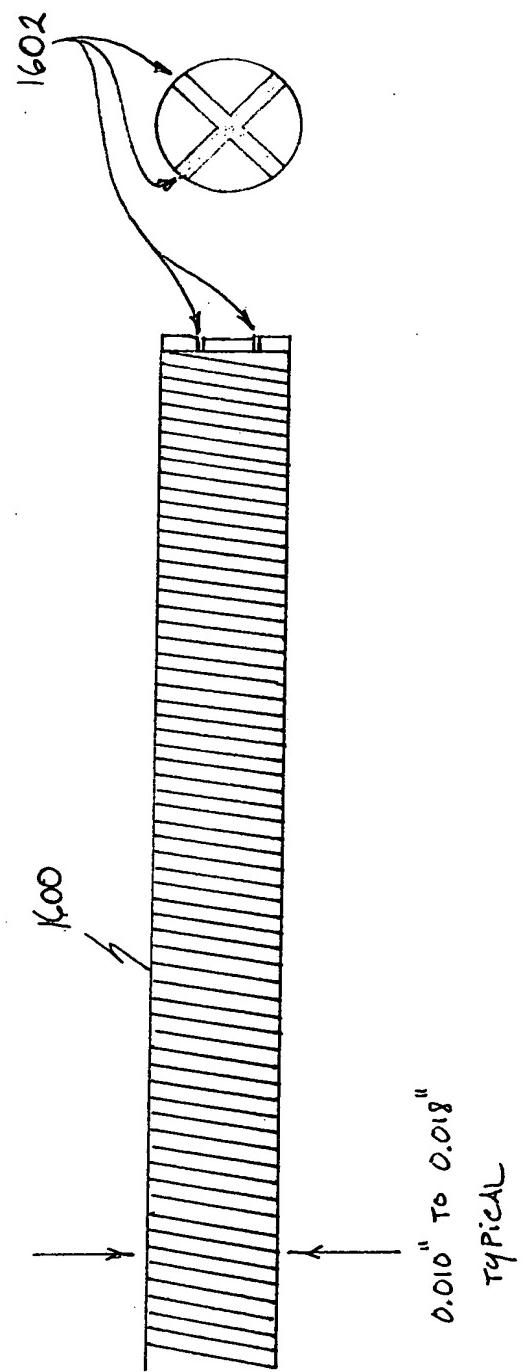


FIGURE 16



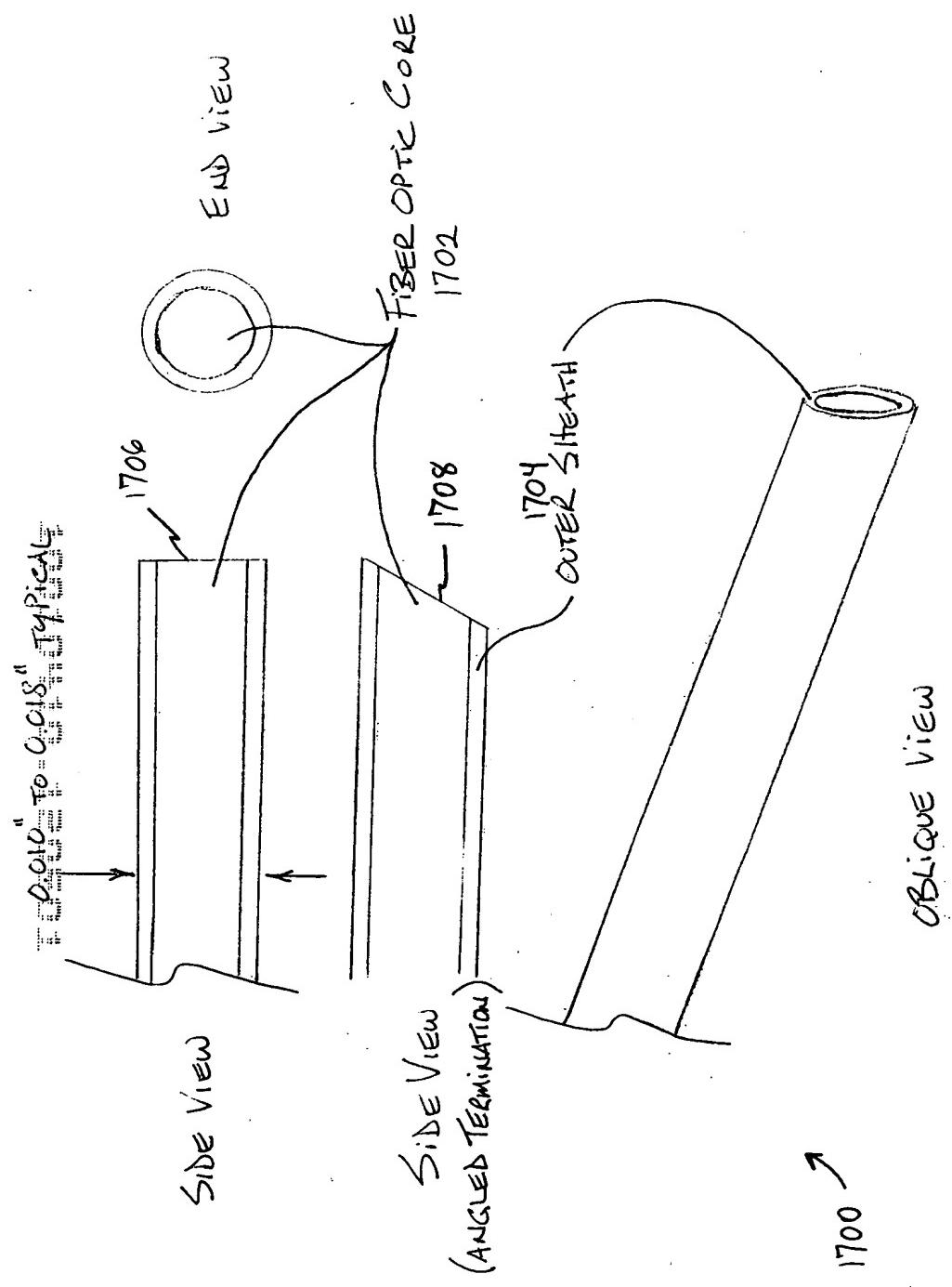


FIGURE 17A

1750
↓

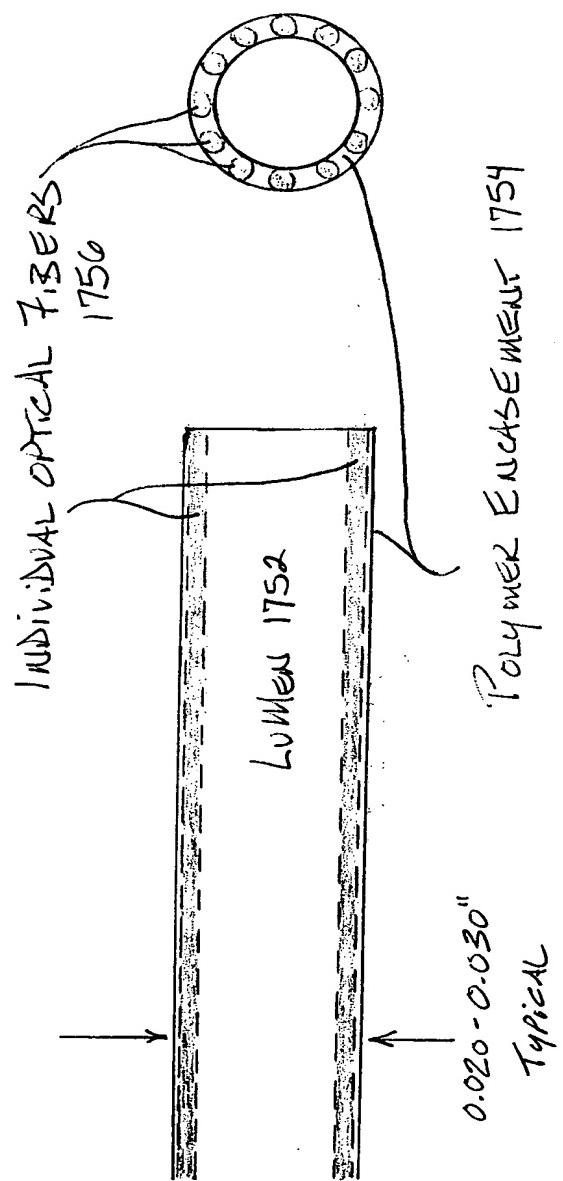


Figure 17B

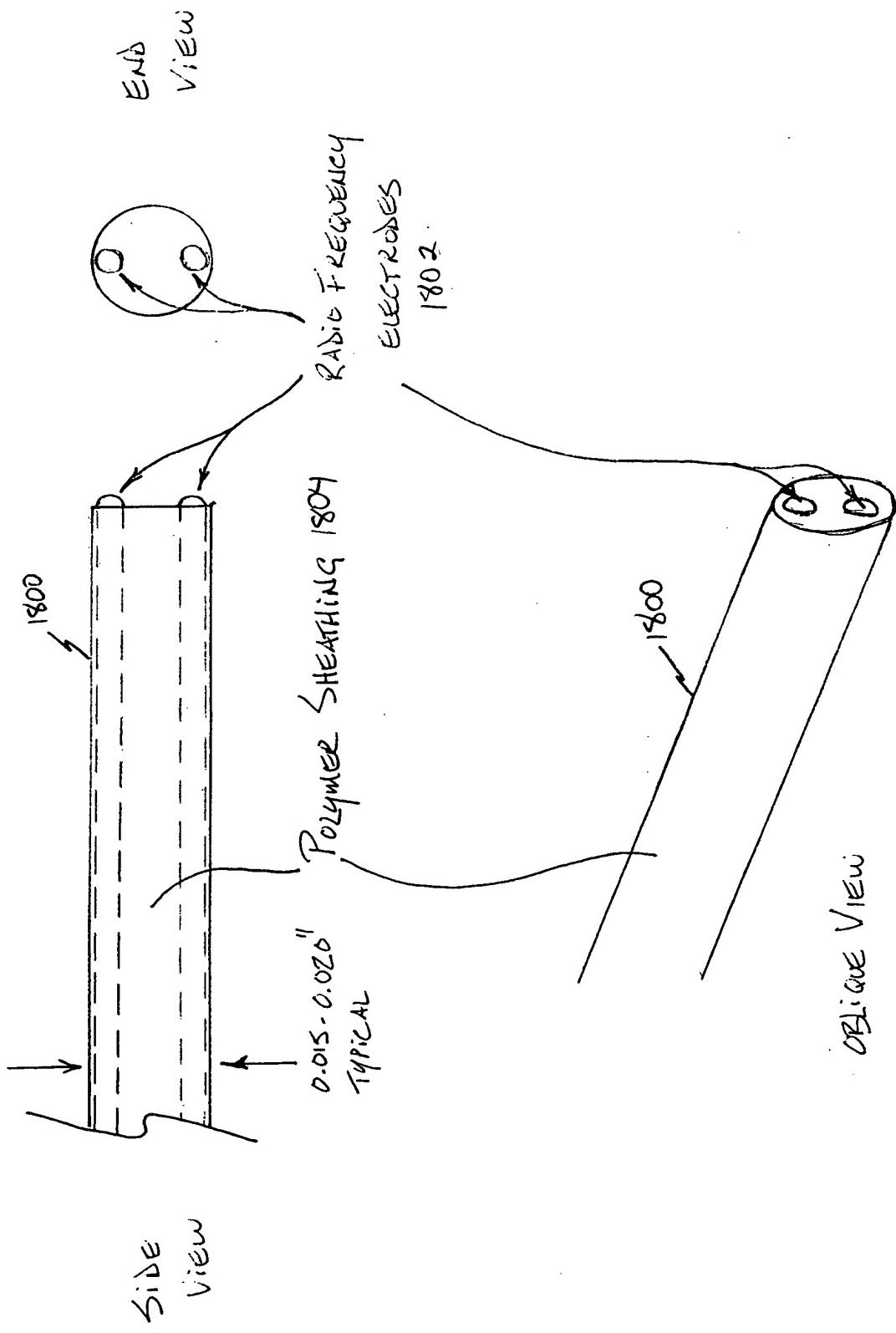


FIGURE 18

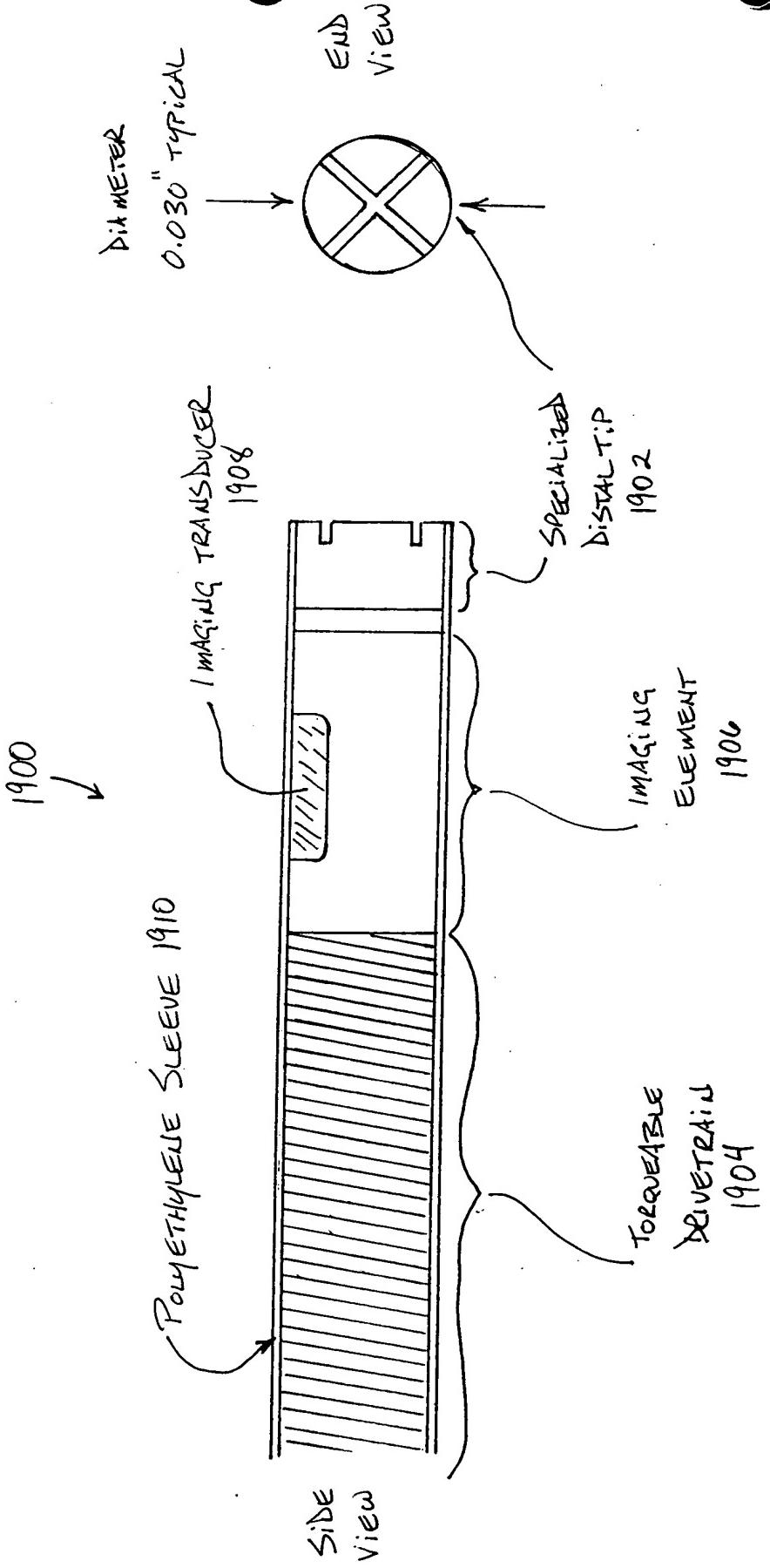


FIGURE 19

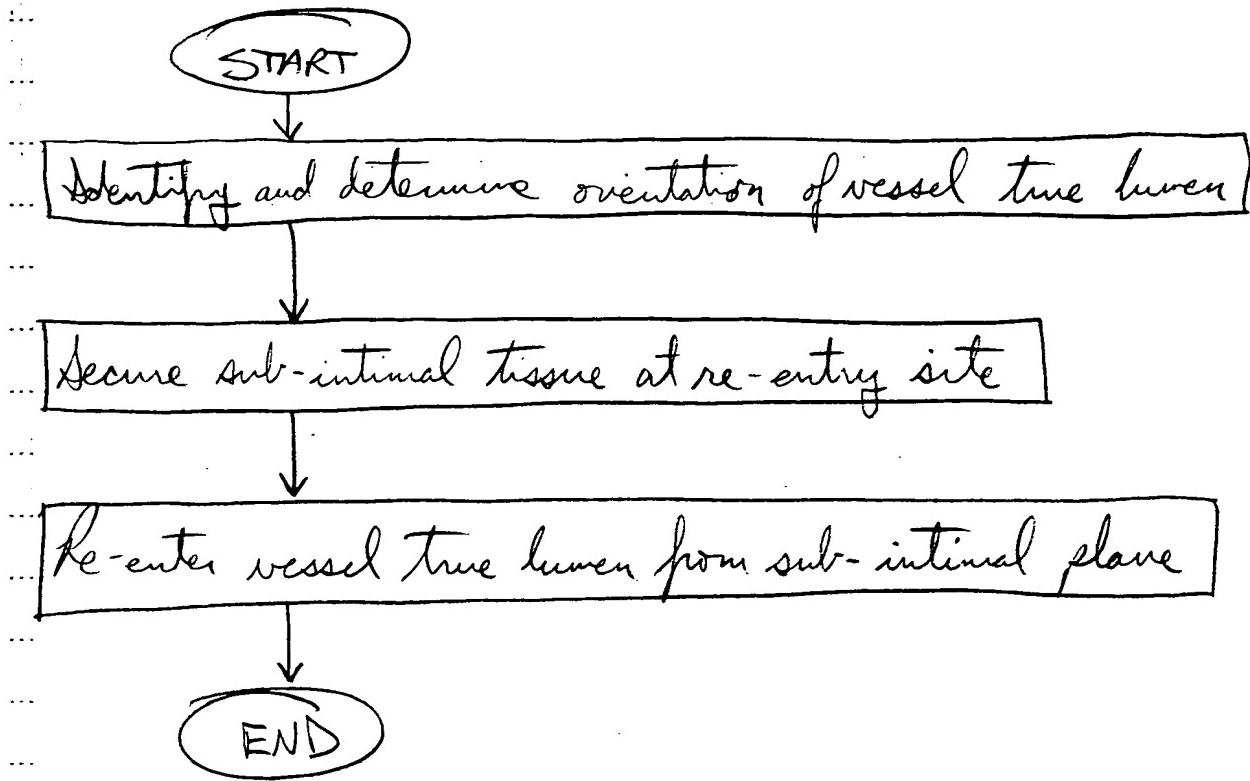


FIGURE 20

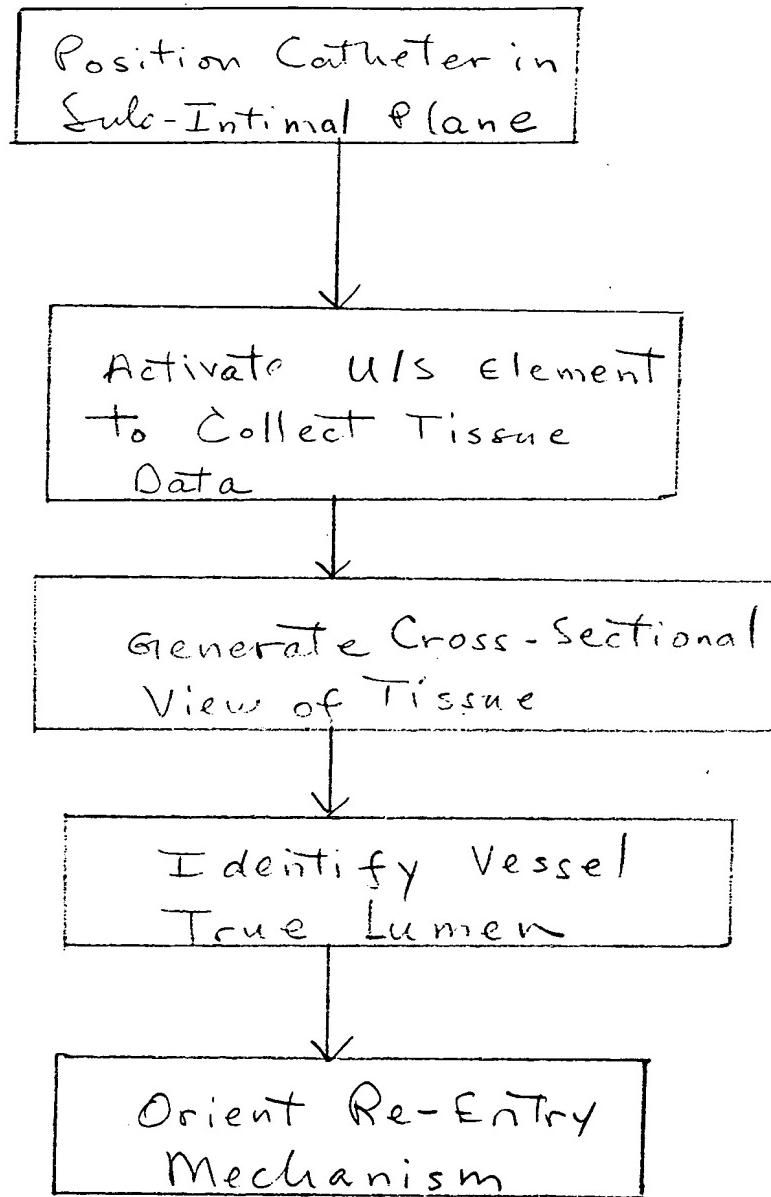


Figure 21

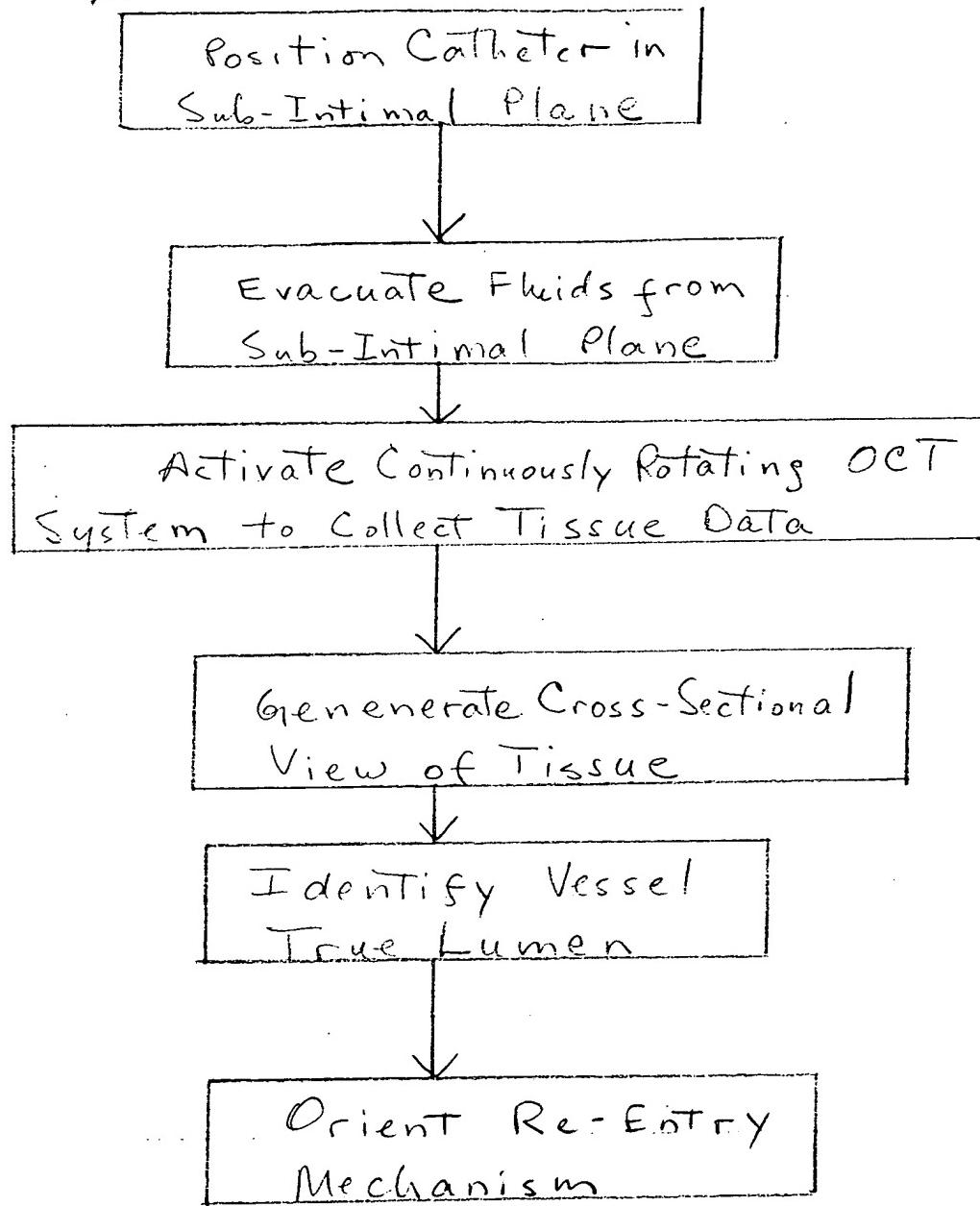


Figure 22

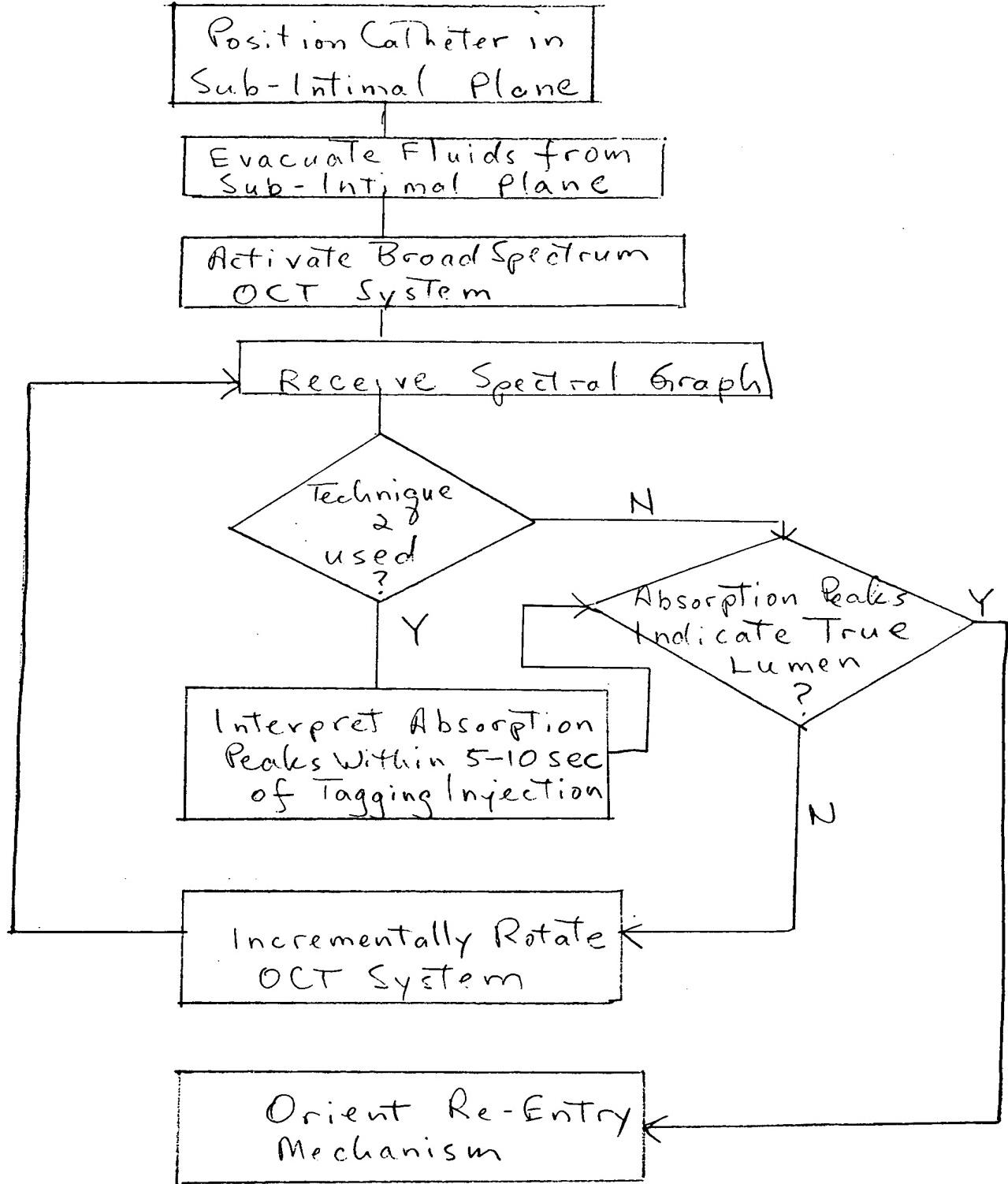


FIGURE 23

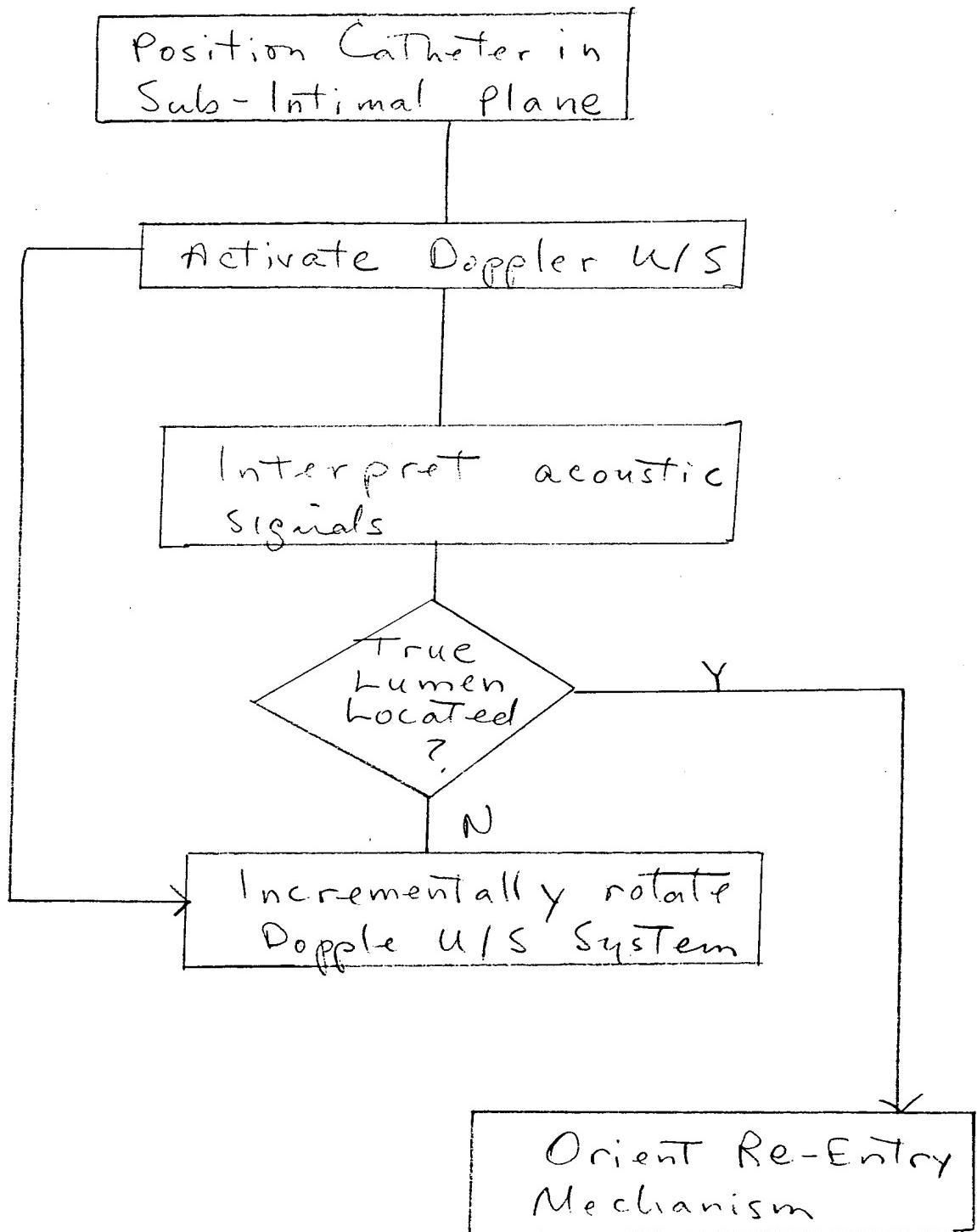


Figure 24

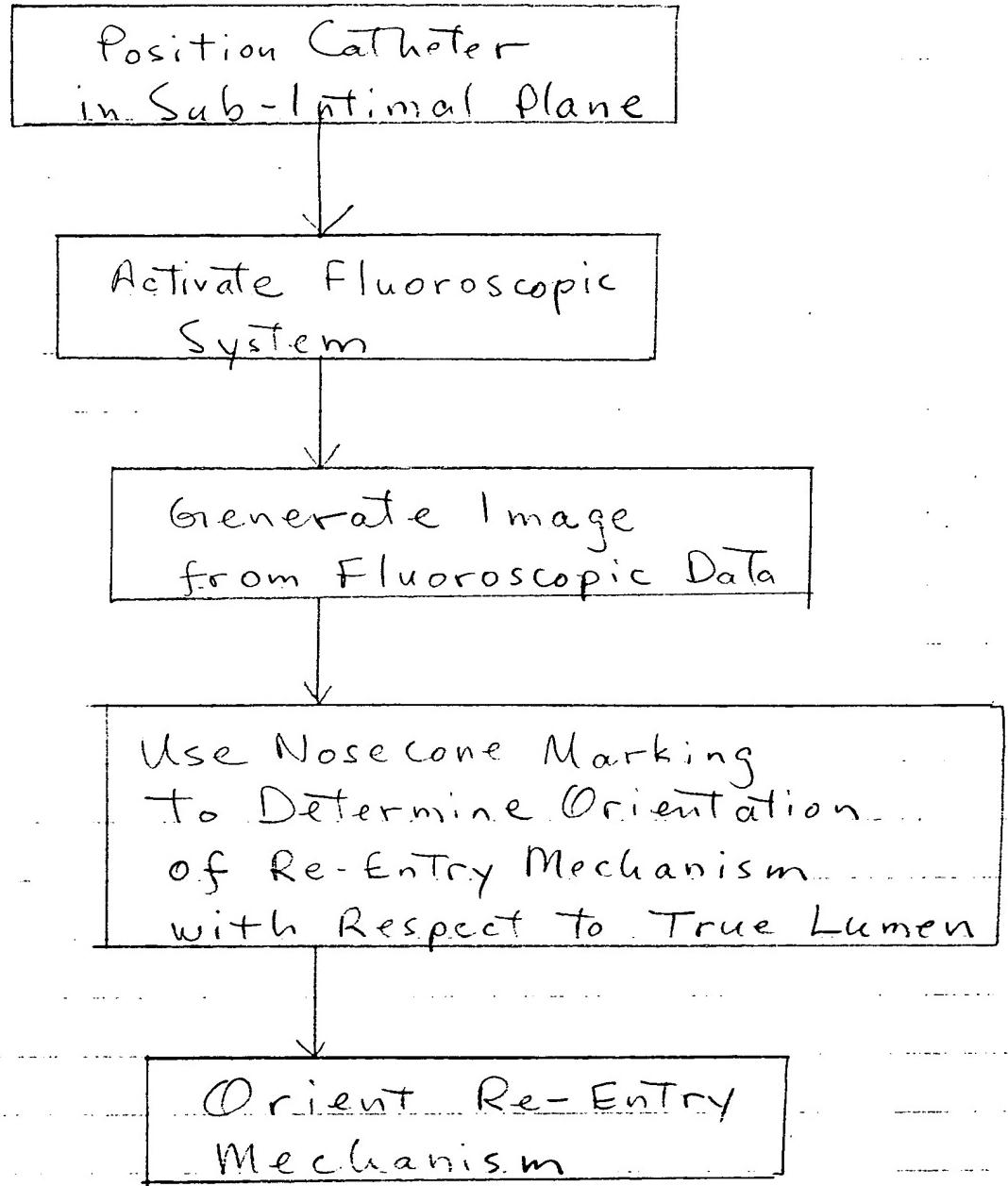


Figure 25.

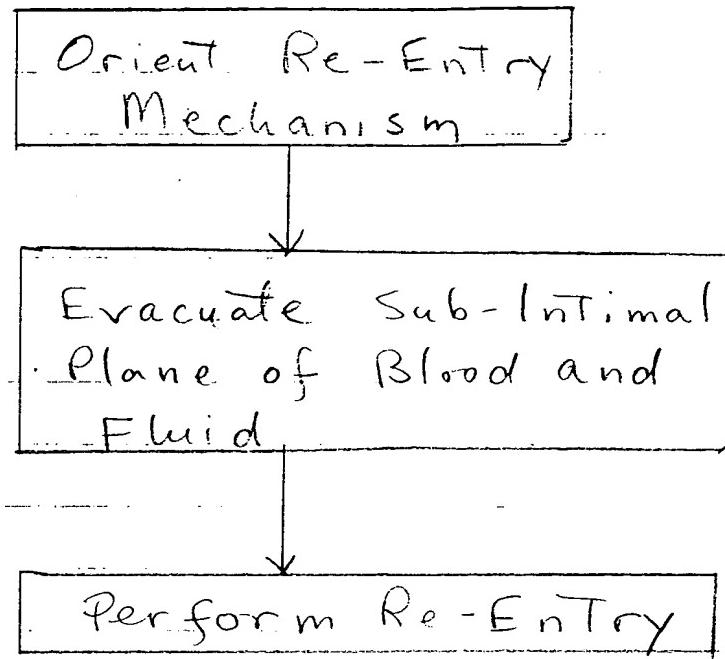


Figure 26

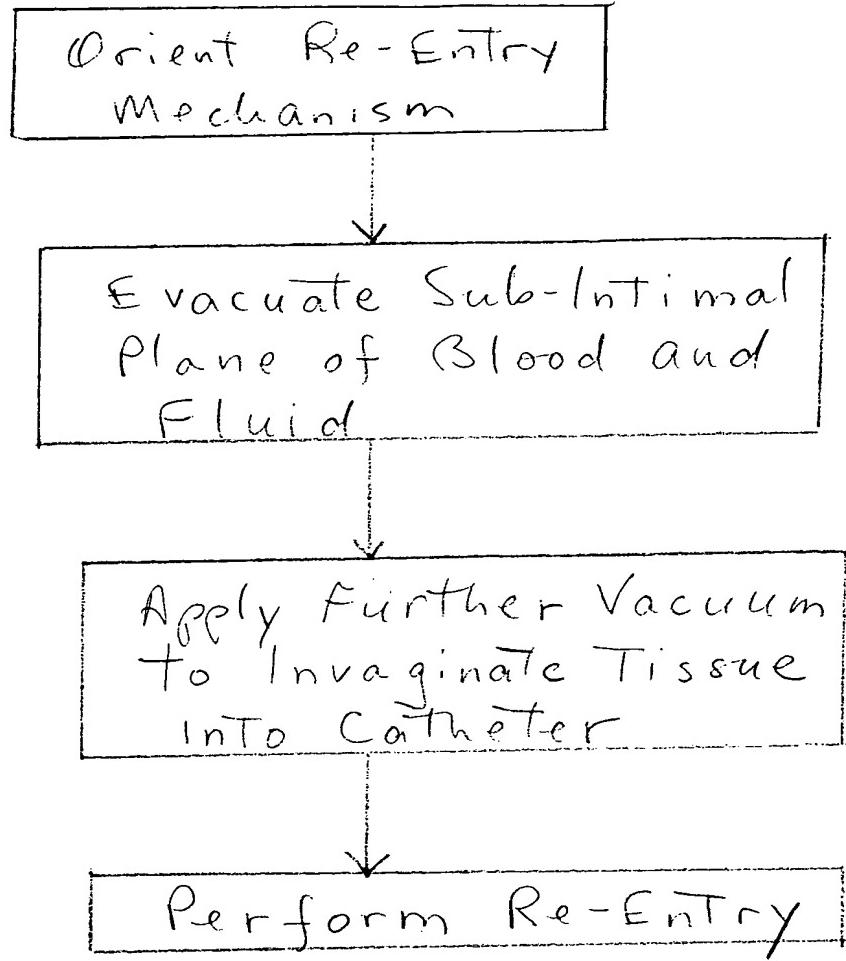


Figure 27

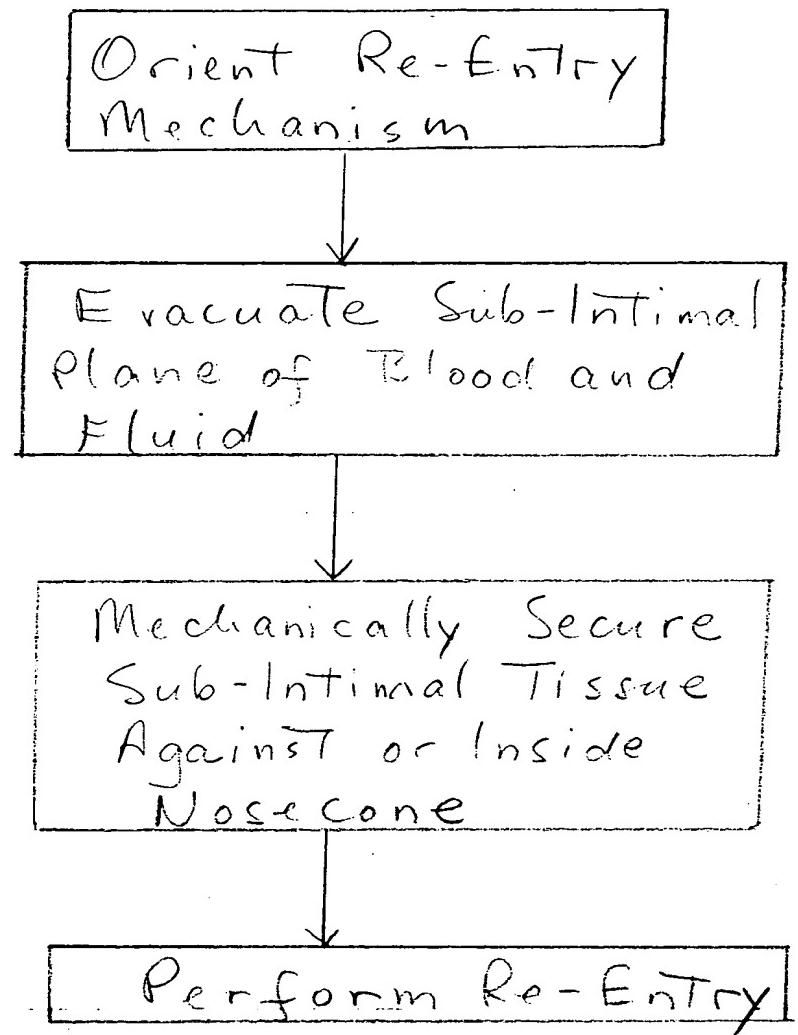


Figure 28

- Position cutting element to cover side port
- Position catheter in vasculature using guide wire
- Replace guide wire with imaging element
- Expose side port
- Position side port with respect to true lumen
- Invaginate sub-intimal tissue into sideport
- Propagate incision through sub-intimal Tissue
- Advance guide wire into true lumen
- Retract catheter

FIGURE 29

- Position guide wire in sub-intimal space
- ↓
- Retract cannula
- ↓
- Position catheter in vasculature
- ↓
- Position side port with respect to true lumen
- ↓
- Position guide wire proximal to nosecone distal end
- ↓
- Lock sub-intimal tissue onto nosecone surface using vacuum
- ↓
- Advance cannula distally and guide out of side port via nosecone internal ramps
- ↓
- Pierce sub-intimal tissue
- ↓
- Advance guide wire into true lumen
- ↓
- Retract cannula

FIGURE 30

- Position guide wire in sub-intimal space
- Remove pierce element and retract forceps
- Position catheter in vasculature at re-entry site
- Remove guide wire and load pierce tool
- Position side port with respect to true lumen
- Invaginate sub-intimal tissue into side port
- Seize sub-intimal tissue using skewers/forceps
- Advance pierce tool to pierce pathway through sub-intimal tissue
- Advance guide wire into true lumen

FIGURE 31

- Position catheter in vasculature using guide wire
- Remove guide wire and advance visualization element
- Align side port with respect to vessel true lumen
- Lock sub-intimal tissue on surface of catheter using applied vacuum
- Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 32

Position catheter in vasculature using guide wire

Remove guide wire and replace with specialized
guide wire

Activate visualization element

Align side port with respect to vessel true lumen

Invaginate sub-intimal tissue into nosecone

Push and/or rotate guide wire distal tip through
sub-intimal tissue into vessel true lumen

FIGURE 33

Retract cannula

Position catheter in vasculature using guide wire

Align side port with respect to true lumen

Position guide wire proximal to nosecone distal end

Lock sub-intimal tissue onto nosecone using vacuum

Advance cannula distally along internal ramp until in secure purchase with sub-intimal tissue

Advance guide wire until tip coincident with cannula distal tip

Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 34

Position catheter in vasculature with respect to
vessel true lumen

↓
Advance specialized guide wire proximally relative to
distal end of nose cone

↓
Lock sub-intimal Tissue onto nosecone using vacuum

↓
Rotate/advance specialized guide wire to engage
internal rails of nosecone

↓
Push and/or rotate guide wire distal tip through sub-
intimal tissue into vessel true lumen

↓
Advance specialized guide wire further distally until
tapered section translates through nosecone slot into
nosecone distal end port

↓
Retract catheter

FIGURE 35

Position catheter in vasculature with respect to vessel true lumen

Retract guide wire and advance visualization element

Rotate side port to face re-entry site

Remove visualization element and advance guide wire

Lock sub-intimal tissue onto nosecone using vacuum

Advance guide wire into nosecone until in contact with sub-intimal tissue

Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

Retract catheter

FIGURE 36

Position guide wire appropriately in vasculature

↓
Retract push tube

↓
Advance catheter to vascular region of occlusion over the
guide wire

↓
Control guide wire deployment angle from nose cone
with position of push tube

↓
Advance push tube distally to position guide wire at
re-entry site

↓
Push guide wire through sub-intimal tissue into
vessel lumen

FIGURE 37

- Position guide wire appropriately in vasculature
- ↓
- Advance catheter over guide wire to vascular region of occlusion
- ↓
- Retract guide wire distal end into catheter, allowing "J" tip to re-form
- ↓
- Align catheter with respect to re-entry site
- ↓
- Apply vacuum to evacuate sub-intimal plane
- ↓
- Advance guide wire into contact with sub-intimal tissue
- ↓
- Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen
- ↓
- Retract catheter

FIGURE 38

Retract push tube

↓
Advance catheter over guide wire to vascular region of occlusion

↓
Retract guide wire to a position proximal to the internal ramp

↓
Align catheter with respect to re-entry site

↓
Evacuate sub-intimal plane using vacuum

↓
Advance push tube to deploy internal push ramps

↓
Advance guide wire into contact with sub-intimal tissue via deployed push ramps

↓
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

↓
Retract catheter

FIGURE 39

Load a first lumen with working element

Advance catheter over guide wire to vascular region of occlusion using a second lumen

Retract guide wire distal end into catheter, allowing "J" tip to re-form

Align catheter with respect to re-entry site

Evacuate sub-intimal plane

Establish path into vessel true lumen using working element

Retract working element

Advance guide wire into vessel true lumen

Retract catheter

FIGURE 40

Load a first lumen with visualization element

Advance catheter over guide wire to vascular region of occlusion using a second lumen

Remove guide wire and replace with re-entry wire

Advance visualization element into distal single lumen

Align catheter with respect to re-entry site

Retract visualization element to dual lumen region

Evacuate sub-intimal plane

Establish path into vessel true lumen using re-entry wire

Remove re-entry wire and replace with guide wire into vessel true lumen

Retract catheter

FIGURE 41

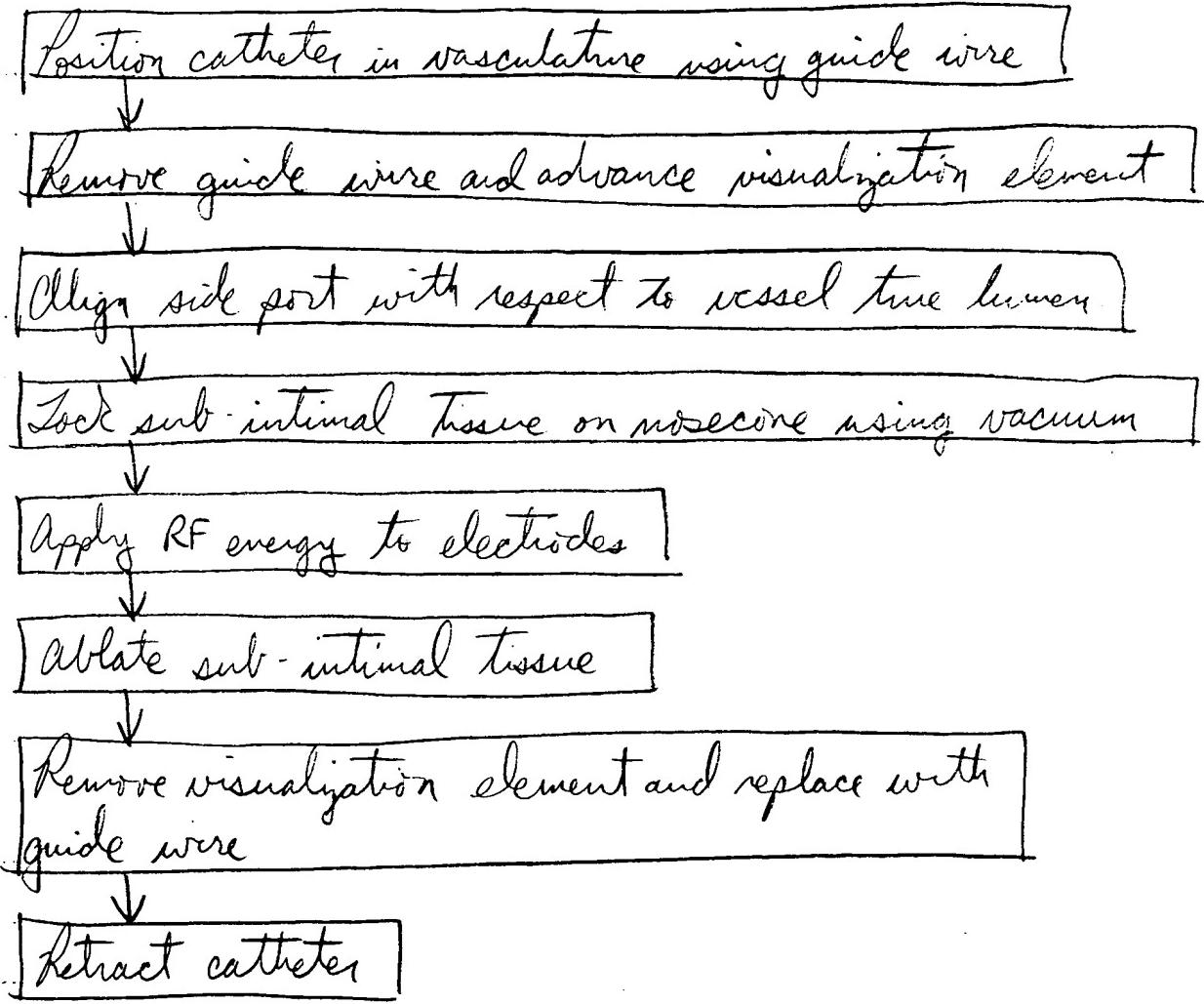


FIGURE 42

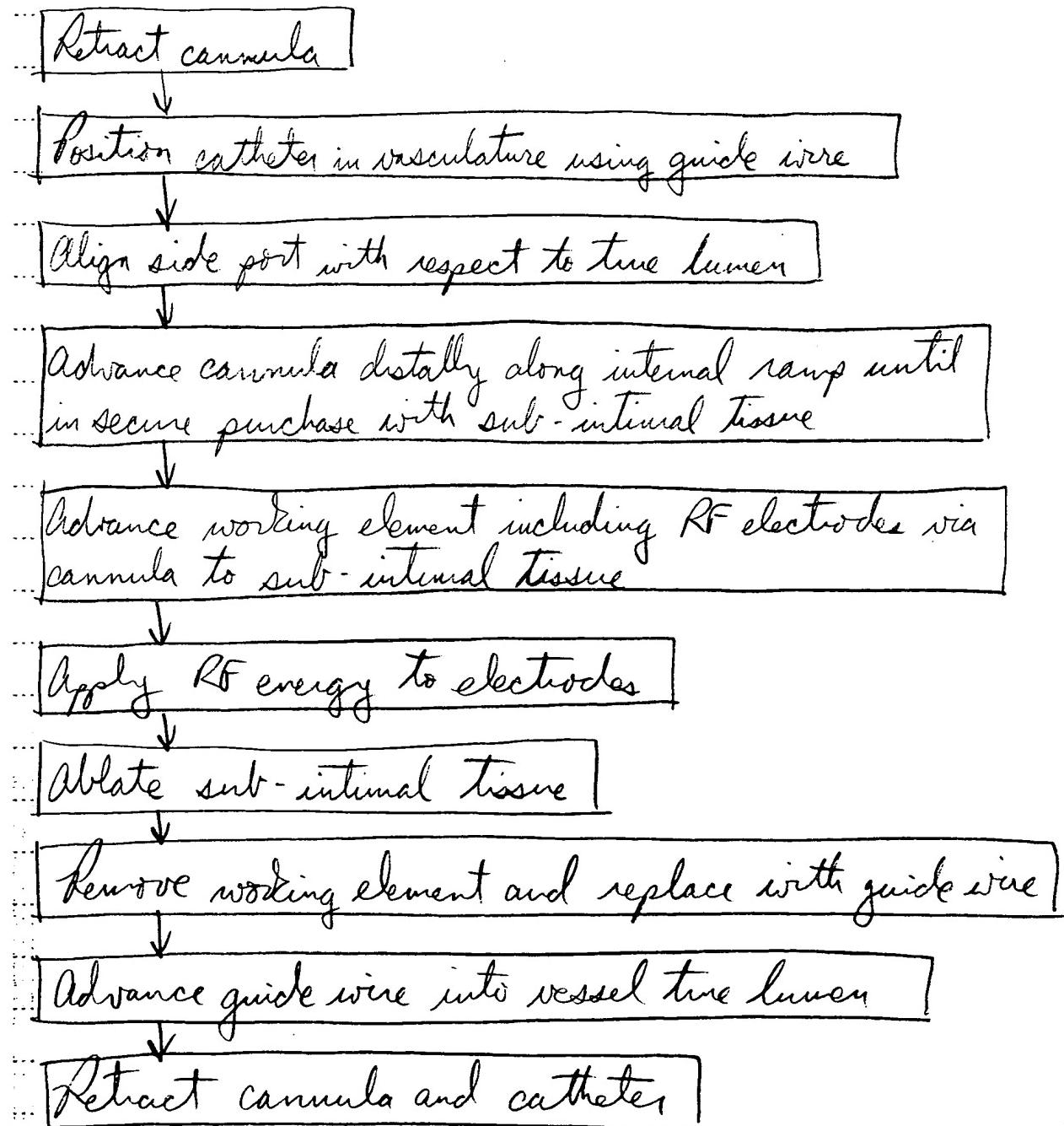


FIGURE 43

- Position catheter in vasculature using glide wire
- Retract glide wire and advance visualization element
- Position side port to face re-entry site
- Remove visualization element and advance RF working element
- Lock sub-intimal tissue onto nosecone
- Apply RF energy to electrodes
- Advance RF working element to ablate sub-intimal tissue
- Remove RF working element and replace with glide wire
- Advance glide wire into vessel true lumen
- Retract catheter

FIGURE 44

- Position guide wire in vasculature
- Retract push tube
- Advance catheter to vascular region of occlusion over the guide wire
- Remove guidewire and replace with RF working element
- Control RF working element deployment angle from nose cone with position of push tube
- Advance push tube distally to position RF electrodes at re-entry site
- Apply RF energy to ablate sub-intimal tissue
- Remove RF working element and replace with guide wire
- Advance guide wire into vessel true lumen
- Retract catheter

FIGURE 45

Load optical fiber system into catheter lumen

↓
Advance catheter to vascular region of occlusion over guide wire using visualization lumen

↓
Remove guide wire and replace with visualization element

↓
Advance optical fiber system until the distal termination is coincident with lateral exit port

↓
Align catheter relative to vessel re-entry site

↓
Apply vacuum to evacuate dissection plane and lock sub-intimal tissue onto catheter surface

↓
Apply laser energy to optical fiber system

↓
Ablate sub-intimal tissue at re-entry site

↓
Remove optical fiber system and replace with guide wire

↓
Advance guide wire into true vessel lumen

FIGURE 46

- Remove optical fiber system from catheter
- Advance catheter to vascular region of occlusion over guidewire
- Remove guide wire and replace with optical fiber system
- Align catheter relative to vessel true lumen using visualization system
- Evacuate dissection plane using vacuum
- Apply laser energy to ablate sub-intimal tissue at re-entry site
- Remove optical fiber system and replace with guide wire
- Advance guide wire into true vessel lumen

FIGURE 47

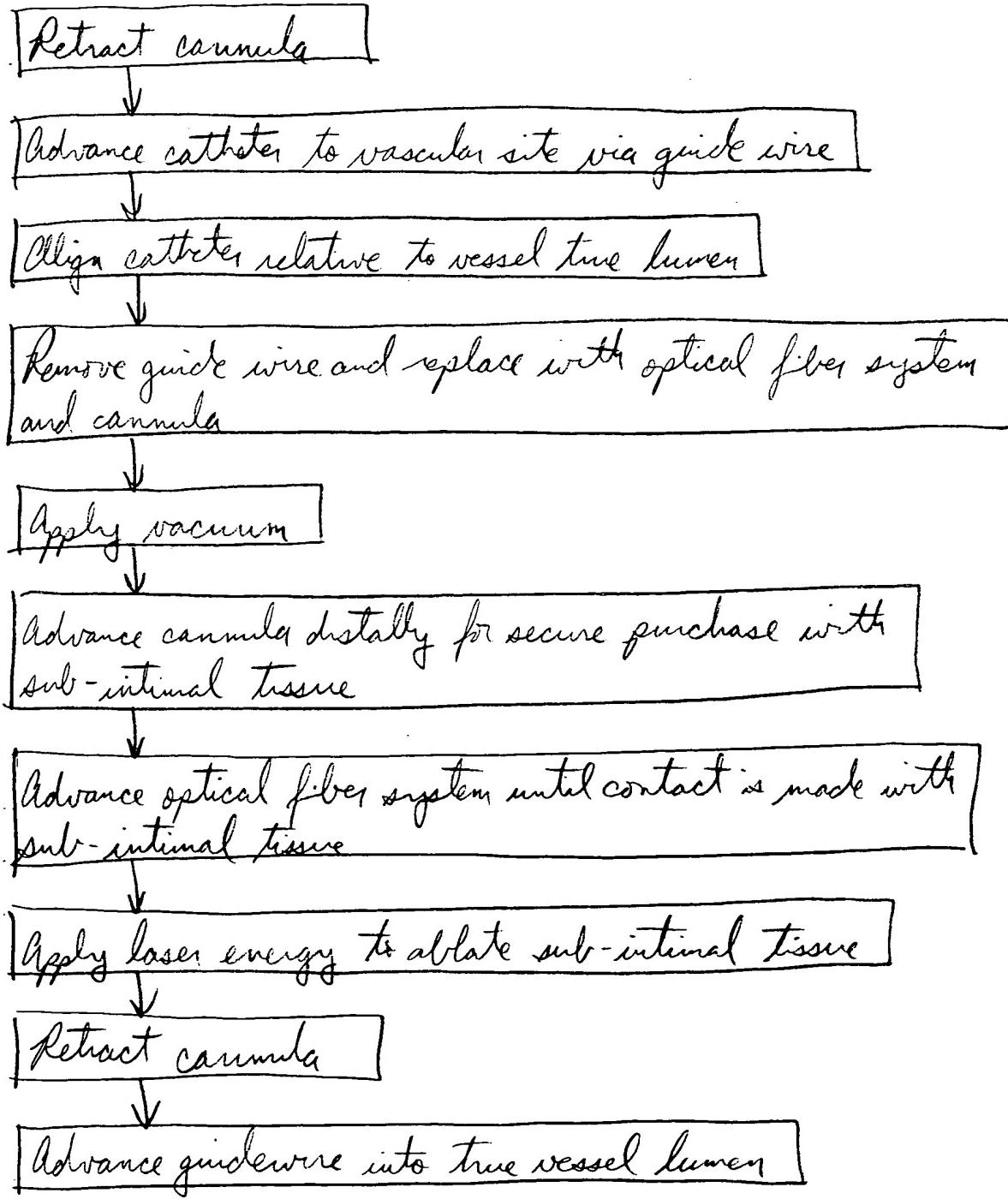
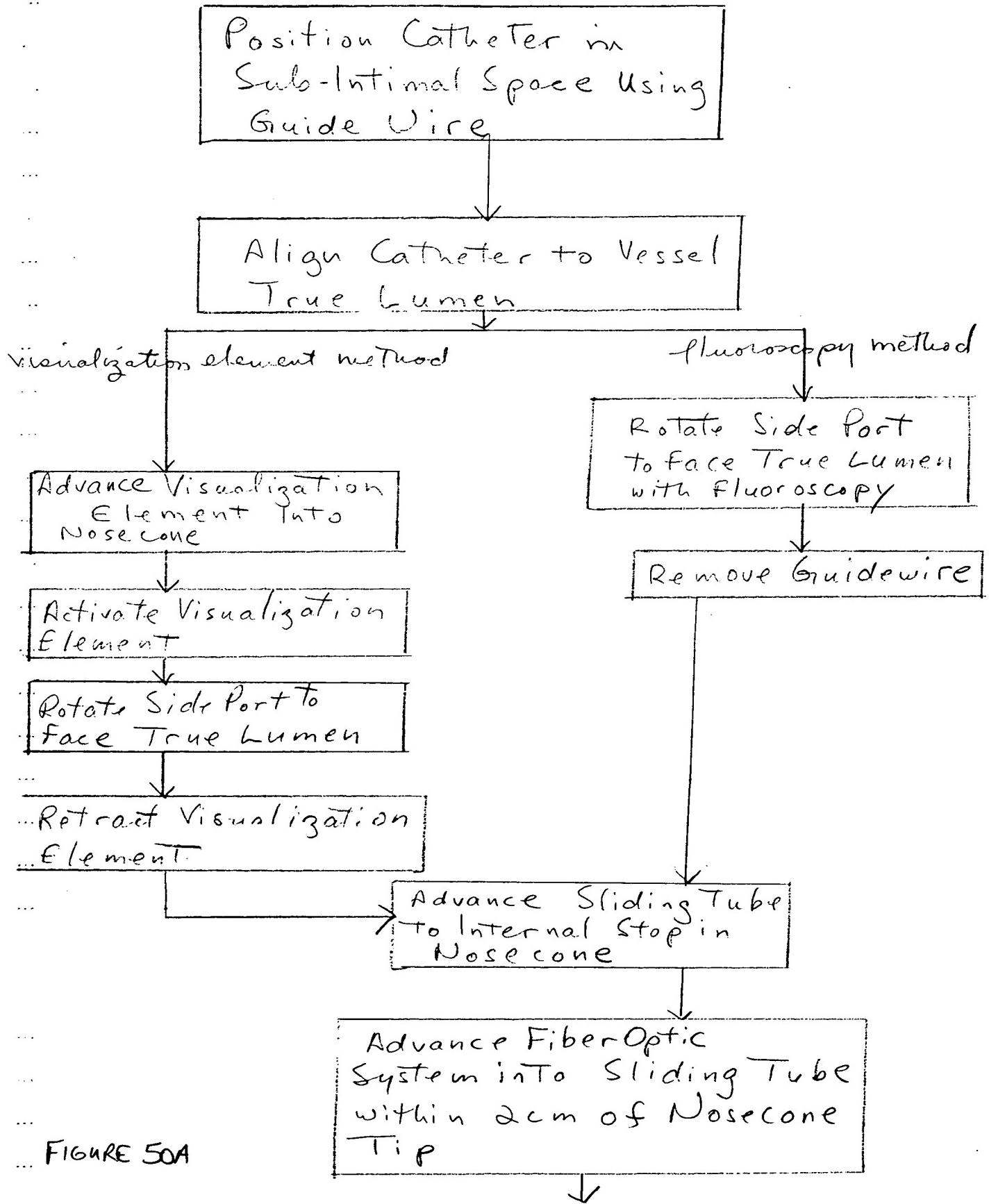


FIGURE 48

- Advance catheter to vascular site via guide wire
- Align catheter relative to vessel true lumen
- Remove guide wire and replace with optical fiber system
- Apply vacuum
- Advance optical fiber system through nosecone and into contact with sub-intimal tissue
- Apply laser energy to ablate sub-intimal tissue
- Remove optical fiber system and replace with guidewire
- Advance guide wire into true vessel lumen
- Retract catheter

FIGURE 49



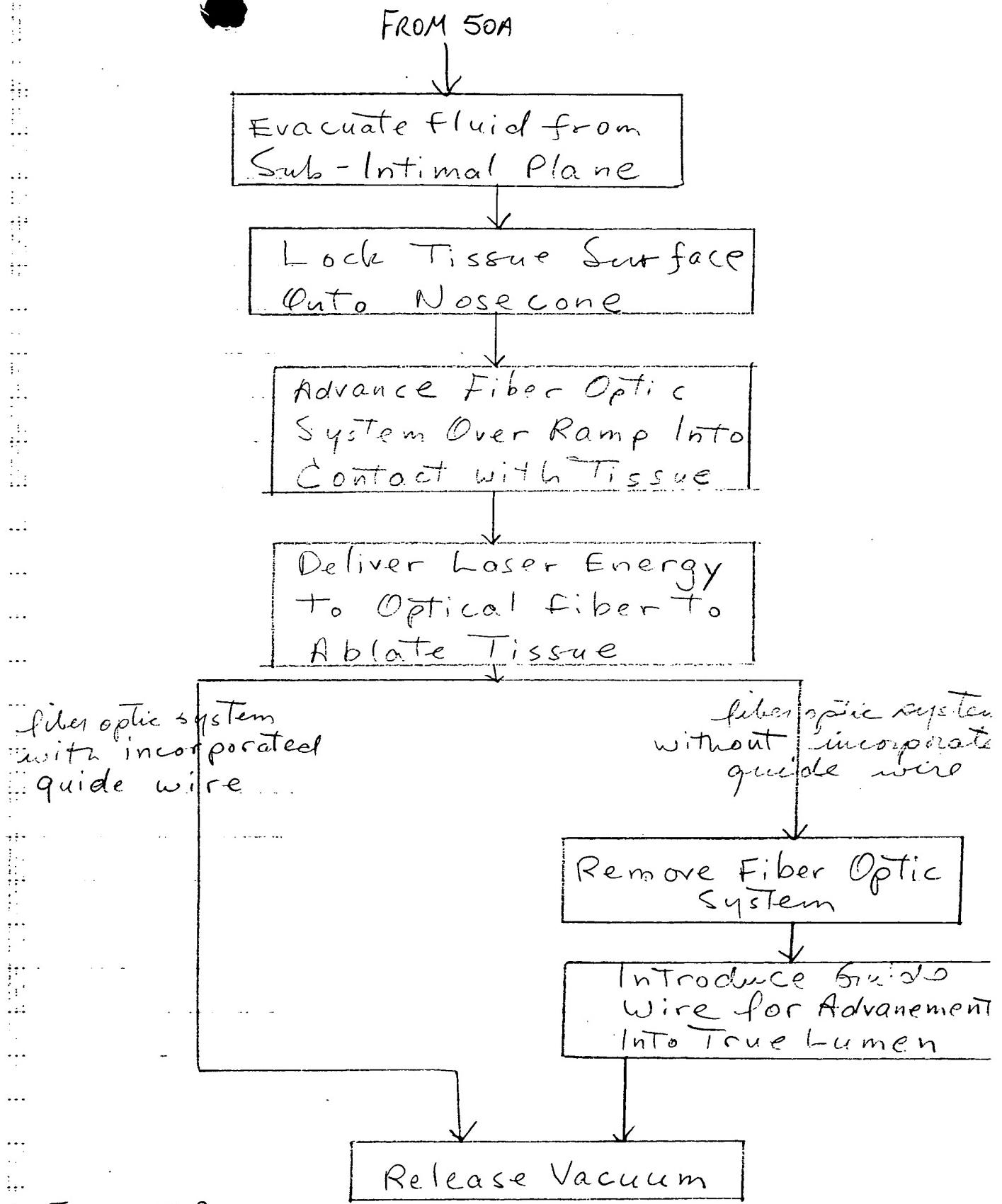


FIGURE 5aB

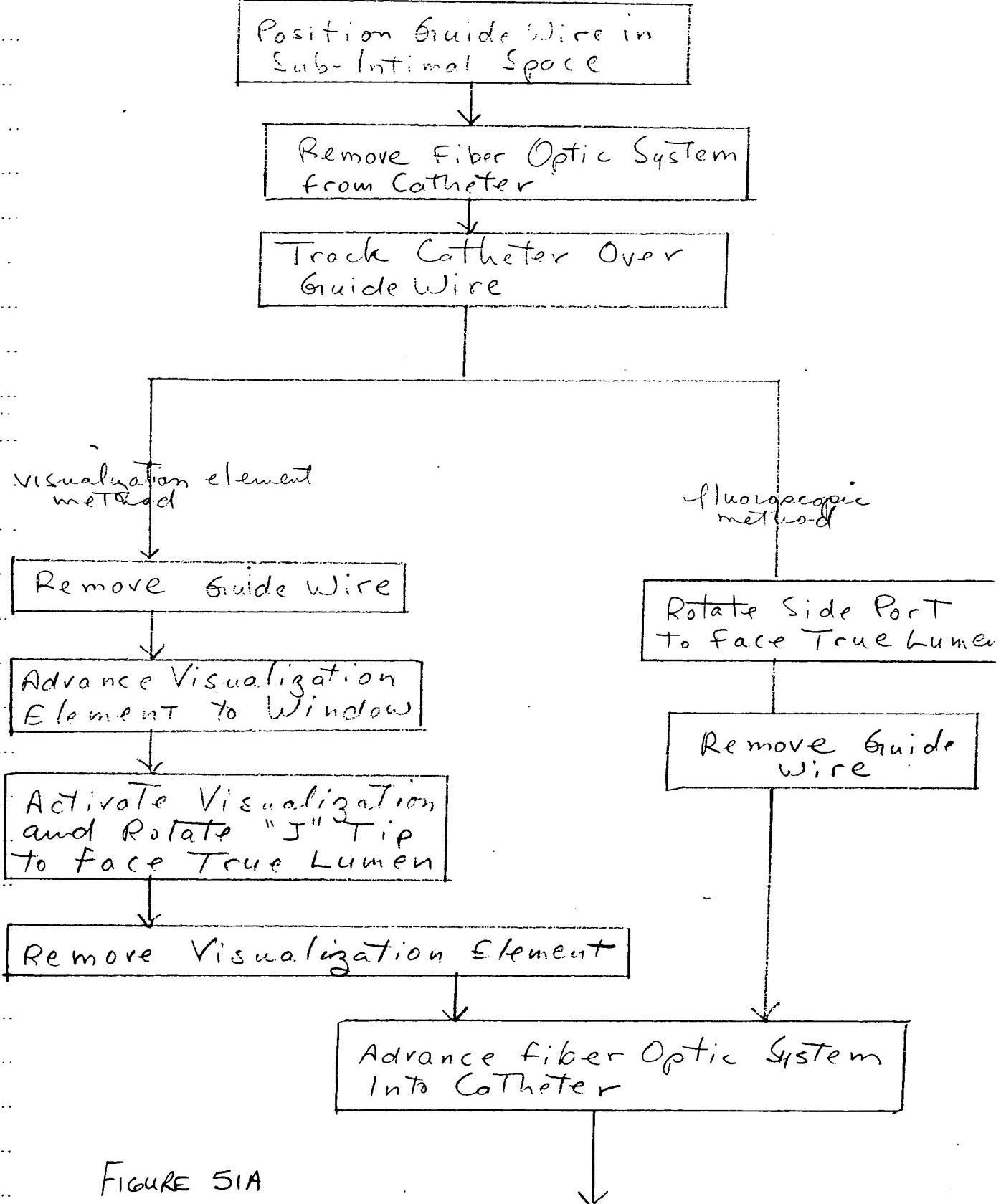


FIGURE S1A

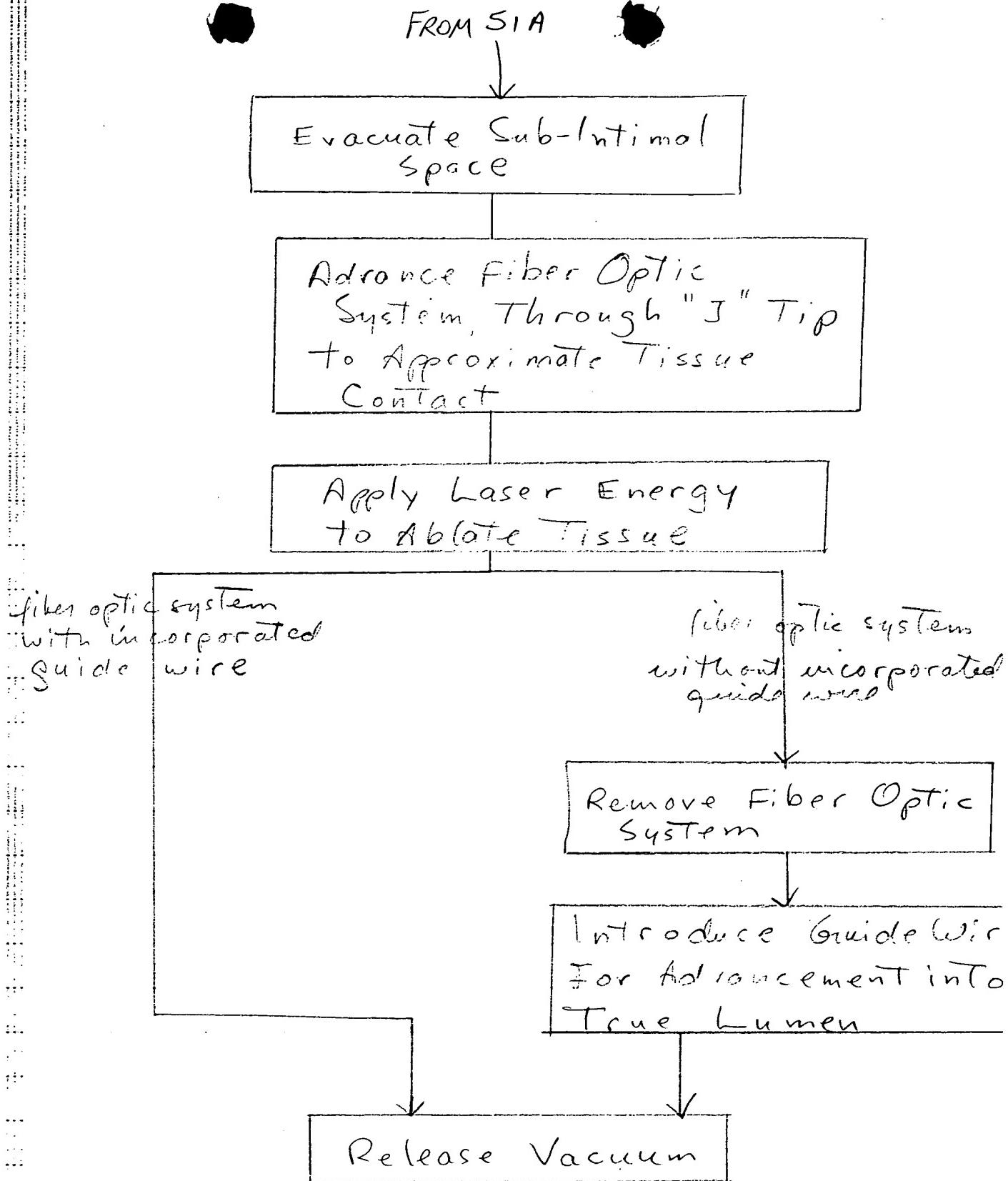


FIGURE 51B

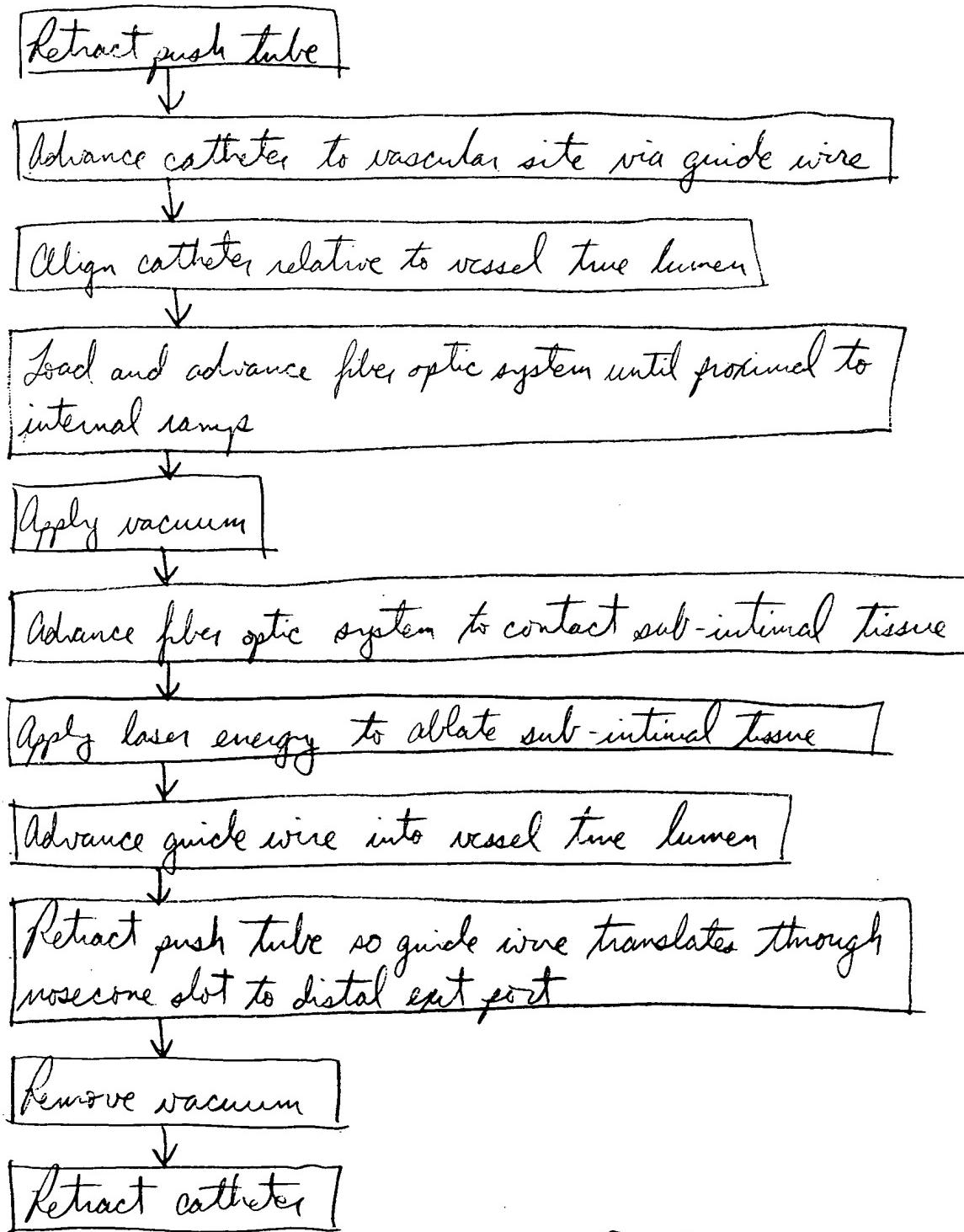


FIGURE 52